2013-1576, -1577

United States Court Of Appeals for the Federal Circuit

WARSAW ORTHOPEDIC, INC.,
Plaintiff/Counterclaim Defendant-Appellant,

and

MEDTRONIC SOFAMOR DANEK USA, INC.,
Counterclaim Defendant-Appellant,

and

MEDTRONIC PUERTO RICO OPERATIONS CO. and MEDTRONIC SOFAMOR DANEK DEGGENDORF, GMBH,
Counterclaim Defendants,

v.

NUVASIVE, INC,
Defendant/Counterclaimant-Cross-Appellant,

APPEALS FROM THE U.S. DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA IN CASE NO. 08-CV-1512, JUDGES CATHY ANN BENCIVENGO AND MICHAEL M. ANELLO

NUVASIVE'S OPENING BRIEF

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February 3, 2014

CERTIFICATE OF INTEREST

Counsel for NuVasive, Inc., certifies the following:

1. The full name of every party or amicus represented by me is: NuVasive, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: N/A.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are: N/A.

4. N/A. There is no such corporation as listed in paragraph 3.

5. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

> Fish & Richardson P.C.: *Craig R. Compton, Frank E. Scherkenbach, *John E. Gartman, Keeley Vega, Kelly C. Hunsaker, *Kimberly Kennedy, Michael E. Florey, *Nicholas V. Martini, *Thomas S. McClenahan, Todd G. Miller, Craig E. Countryman, John M. Farrell, Jonathan J. Lamberson, and Neil Warren.
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Dated: February 3, 2014

/s/ Craig E. Countryman
Craig E. Countryman

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STATUTES

STATEMENT OF RELATED CASES

Pursuant to Fed. R. App. P. 47.5, counsel for NuVasive states that there was an earlier appeal and cross-appeal in this case, which a motions panel of this Court, consisting of Judges Lourie, Schall, and Dyk, dismissed as premature on August 2, 2012, because the ongoing royalty rate had not yet been set by the district court. *See Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, Appeal Nos. 2012-1263, -1266. There have been no other appeals in or from the same civil action or proceeding in the lower court previously before this or any other appellate court.

There is no case known to counsel to be pending in this court that will directly affect or be directly affected by this Court's decision. There is one other district court case between these parties—*Warsaw Orthopedic, Inc. et al. v. NuVasive, Inc.*, Case No. 12-cv-02738-CAB (MDD) (S.D. Cal.)—that may be impacted by the Court's decision in this appeal

Moreover, there are two pending *inter partes* reviews in the PTO regarding Warsaw's U.S. Patent 8,251,997, which is related to Warsaw's '973 patent in this case. The PTO's opinion granting review of the '997 patent rejected the interpretation of a prior art reference (the Brantigan '327 patent) that Warsaw has advanced in this case, and found that Brantigan '327 teaches an implant that is capable of lateral insertion.

STATEMENT OF JURISDICTION

The district court had jurisdiction over this patent infringement case under 28 U.S.C. §§ 1331 and 1338. The district court entered a final judgment on August 20, 2013. (A78-79.)

NuVasive filed its Notice of Appeal on August 20, 2013, and Warsaw filed its Notice of Appeal on August 20, 2013. (A5885-88, A5889-91.) Both Notices of Appeal were filed within 30 days of the final judgment, making them timely under Federal Rule of Appellate Procedure 4(a)(1)(A). This Court thus has jurisdiction over the appeal and the cross-appeal pursuant to 28 U.S.C. § 1295(a)(1).

STATEMENT OF THE ISSUES FOR NUVASIVE'S CROSS-APPEAL

1. Whether the judgment of no invalidity on the '973 patent can stand where:

    (i) Each element of the asserted claims is present in the prior art commercial Brantigan implants;

    (ii) The Brantigan '327 patent anticipated or rendered obvious each asserted claim; and

    (iii) Warsaw distinguished this prior art by relying only on limitations that are not part of the claims as properly construed by the district court.

2. Whether the asserted '973 claims are indefinite because they purport to cover an apparatus yet implicitly require method steps because they define the implant's dimensions relative to the vertebrae between which it is inserted.

3. Whether the infringement judgment on the '933 patent should be reversed where:

    (i) Warsaw's theory of equivalence vitiated the numerical and structural limitations recited in the claims; and

    (ii) Warsaw relied on different structures to meet the "first and second portions" requirement in different parts of the claims, even though the claims require the same structure to meet this requirement throughout.

4. Whether the entire "lost profits" award should be set aside because Warsaw sought to recover money that other Medtronic entities supposedly would have transferred to Warsaw, rather than its own lost sales revenue.

5. Whether the "lost profits" award should be vacated because Warsaw included hundreds of unpatented items in its calculations.

STATEMENT OF THE ISSUES FOR WARSAW'S APPEAL

1. If this Court affirms the liability judgment on the '973 or '933 patent, whether the district court abused its discretion when denying Warsaw's supplemental damages request.

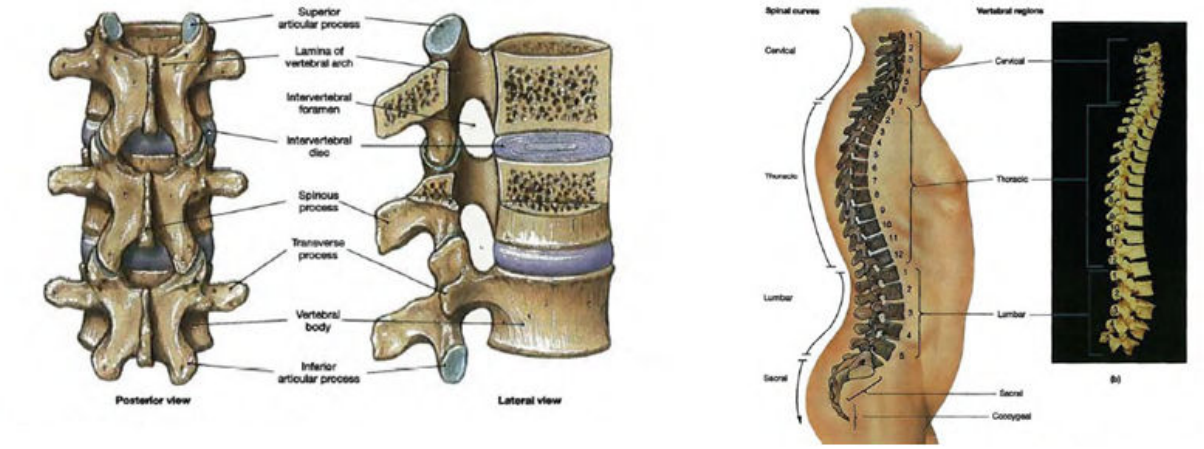
2. If this Court affirms the liability judgment on the '973 or '933 patent, whether the district court abused its discretion in setting an ongoing royalty at a rate higher than the jury's but consistent with the public interest in continued availability of the accused products.

3. Whether the district court correctly construed the claims of the '236 patent, and, if so, whether substantial evidence supports the jury's infringement determination.

STATEMENT OF THE FACTS

I. Technology Background on Spinal Fusion Surgery.

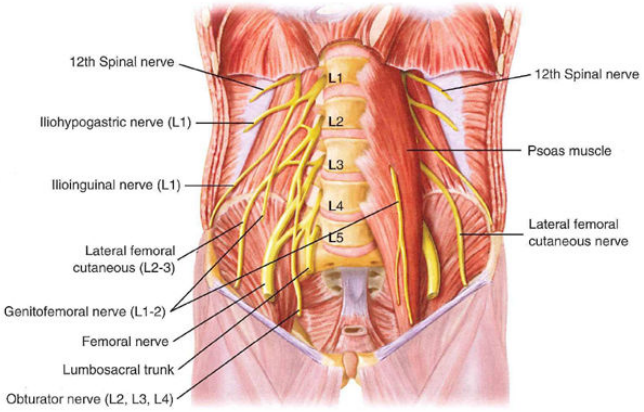
The patents-in-suit relate to various spinal surgery components. The spine includes a vertebral column that is composed of a series of bony vertebral bodies separated by spongy discs. (A1998-99.)



The discs can deteriorate, bulging into surrounding tissue or irritating nearby nerves. One treatment is fusion surgery, in which all or part of the disc is removed and replaced with an implant (which maintains proper separation between the vertebrae) and bone growth material (which promotes fusion between vertebrae). (A10131-32.) Surgeons can optionally install fixation equipment (*e.g.*, rods and screws) separately in patients to further stabilize the spine. (A11186-87.)

There are multiple ways to access the disc space to perform a fusion, including through the patient's front (anterior), back (posterior), or side (lateral). Several references in the 1980s and early 1990s disclosed lateral insertion, (A17429-41 at

A17436, A17438, A17440; A11835-37; A12186-87; A17450-59 at 2:55-59), and the lateral approach had the known benefit of avoiding the aorta or the spinal cord. (A252-53.) But the lateral approach had a major challenge that prevented its widespread use, particularly for the lower, lumbar, spine. (A10367-70, A10470-72.) The lumbar spine is surrounded by the psoas, a nerve-packed muscle:



(A17546.) A surgeon trying to access the disc space through the psoas without guidance has an 80-90% chance of hitting a nerve. (A17634-35, A10472-73.)

NuVasive solved this problem by introducing eXtreme Lateral Interbody Fusion (XLIF) in 2003—the first safe and reproducible lateral procedure that included a nerve-monitoring system. (A10403-04, A10413, A10470-72.) Nerve-monitoring made lateral procedures accessible to all properly trained spine surgeons, not just the few, highly skilled ones who had successfully performed a lateral fusion in the past. (*Id.*) NuVasive's U.S. Patent 7,470,236 covers its first nerve-monitoring algorithm. (A279-300, A10468-71.) NuVasive has other patents on various aspects of XLIF, several of which it currently asserts against Medtronic in another suit.

Contrary to Warsaw's accusations at p. 10-11, XLIF was developed in-house at NuVasive. (A10445-50, A10523, A10569.) NuVasive's efforts had nothing to do with Medtronic's ELIF (Endoscopic Lateral Interbody Fusion)—a procedure that Medtronic abandoned before ever trying it on a live human, because it was unsafe. (A10397, A10445-47, A10472-73.) When Medtronic did introduce a lateral procedure several years later—Direct Lateral Interbody Fusion (DLIF)—surgeons described it as "inferior" and called NuVasive's XLIF procedure "irreplaceable." (A16572-76.)

Medtronic responded to NuVasive's success with XLIF in two ways. It updated DLIF to include better nerve-monitoring technology—technology that infringes NuVasive's '236 patent. (A240.) And a Medtronic-related holding company (Warsaw) filed this suit targeting the implants and retractors used in XLIF.

II. Warsaw's '973 Patent.

A. The '973 Patent Tries to Distinguish Its Implant Based on the "Oversized" Dimensions.

Warsaw's U.S. Patent 5,860,973 is part of a family that includes patents to implants of various sizes and shapes and to various surgical methods. The technology was not developed by Medtronic—it was licensed from Dr. Gary Michelson, who has never performed a lateral fusion on a live human patient. (A10236.) The '973 patent is directed to an implant with a length, width, and height that are defined relative to the dimensions of the space between two adjacent vertebrae. (A243-59.) Its earliest possible priority date is in 1995. (A18873.)

The '973 patent distinguished its implant from the prior art based on size. The patent is directed to an "oversized spinal implant" intended "for insertion from the side of a patient (translateral)." (A243-52 at Abstract, 1:15-18.) The specification contrasts the size of the "translateral spinal fusion implant of the present invention" with prior implants that were inserted from the front or back because "such implants are necessarily limited by the depth, measured from front to back of the vertebrae." (A253 at 3:11-17; *see also* A252 at 2:3-8.) The specification criticizes these prior implants as too small to provide adequate stability for the spine, stressing that the advantage of the "translateral spinal fusion implant of the present invention" is that it "has more surface area of contact" with the vertebrae "and thus permits greater stability so as to withstand torque." (A253 at 3:50-53.)

The prosecution history likewise contrasted prior implants based on size. Responding to an anticipation rejection, the Applicant argued that "[n]one of the implants of the past teach, disclose, or suggest a translateral spinal implant having a length that is substantially greater than one half the transverse width of the vertebrae and the length being substantially greater than the width of the vertebrae." (A31009.) After distinguishing one prior art implant in detail based on size, (A31011), the Applicant concluded that his oversized implant was patentable because it was "being sized to maximize the surface area of contact of the claimed implant between the two adjacent vertebrae" which "permits substantial improvement of the function of Applicant's implant" over the prior art. (A31012.)

The asserted claims—24, 41, 42, 57, and 61—include a non-limiting preamble and a body that recites the "oversized" dimensions the Applicant thought distinguished his implant from the prior art. Claim 35 (from which 41 and 42 depend) is representative and contains the key language related to the parties' validity dispute:

> 35. ***A translateral spinal implant for insertion from the lateral aspect of the spine in the disc space between two adjacent vertebrae, said implant*** having
>
> > a ***length*** that is greater than one half the transverse width of the vertebrae,
> >
> > said ***length*** being substantially greater than the depth of the vertebrae,
> >
> > a height for contacting each of the two adjacent vertebrae, and
> >
> > a width that is at least as great as the height.

(A258 at 13:1-7.) The other claims add prior art structures (*e.g.*, ratchetings to prevent the implant from slipping out and openings for bone growth material). (A257-58.)

The claims define the implant's dimensions relative to the size of the vertebrae between which it is inserted. Nevertheless, the specification explains that a "preferred embodiment" is 42 mm in length, 26 mm in width, and 10-12 mm in height:

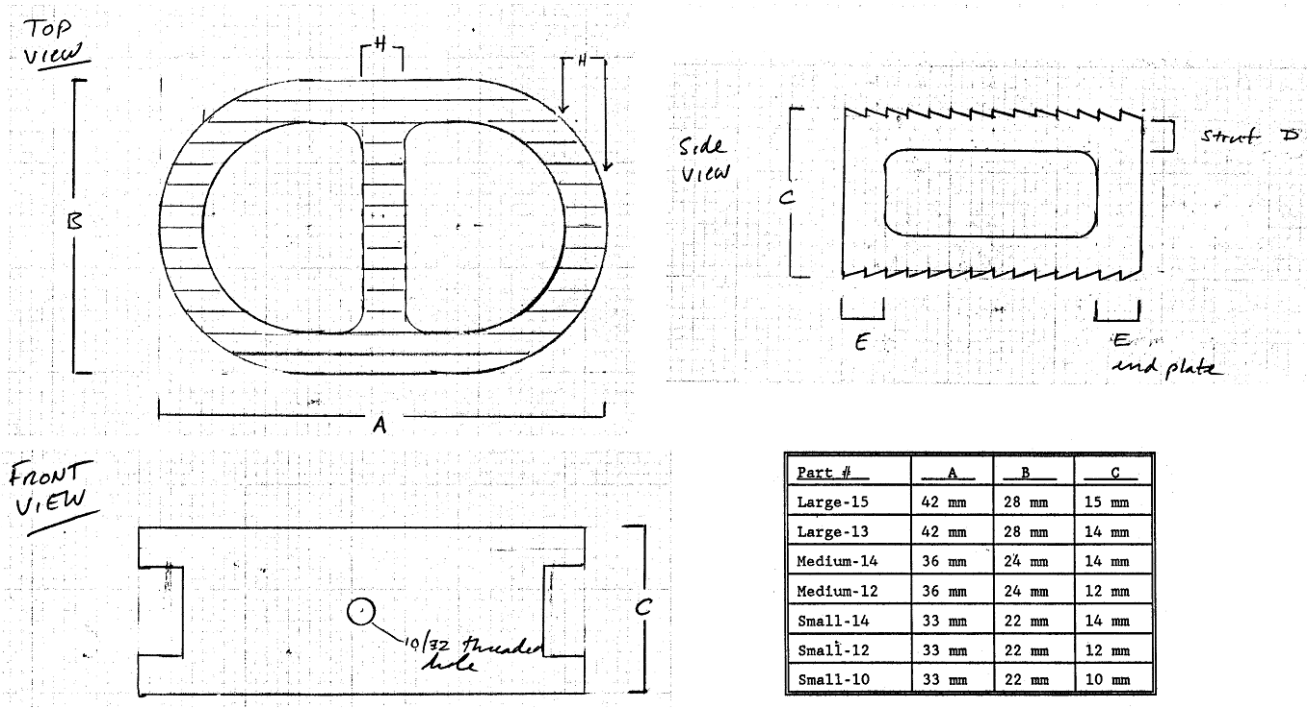
> In the preferred embodiment, the spinal fusion implant 900 has a height in the range of 8 mm to 16 mm, with the preferred height being 10-12 mm; a width in the range of 24 mm to 32 mm, with the preferred width being 26 mm; and a length in the range of 32 mm to 50 mm, with 42 mm being the preferred length.

(A256 at 10:42-47.)

B. The Prior Art Brantigan Commercial Implants Have the Same Dimensions Claimed in the '973 Patent.

There were prior implants with the same dimensions as the '973 claims. By 1990, years before the earliest possible priority date, spine surgeon Dr. John Brantigan had developed and used implants with the same dimensions and structures. (A11459-69, A11480-81, A11499-501, A11504; A15358; A15362-69; A15359-61; A15491-502; A17835-65, A17858; A18873.)

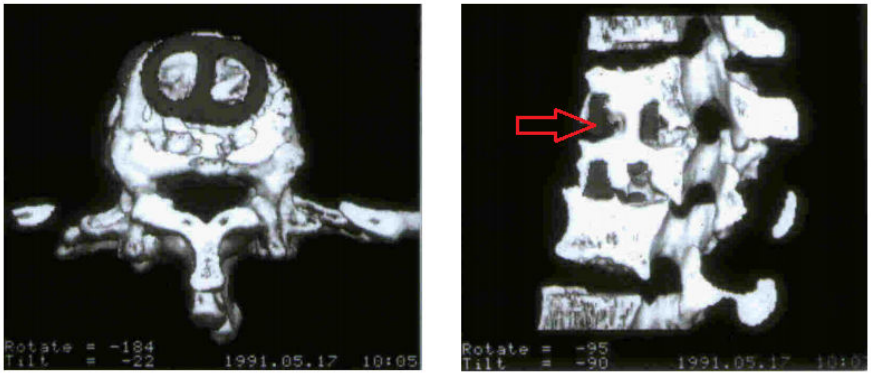
For example, a June 1990 document shows Dr. Brantigan ordering four different implants that fall within the '973 patent's "preferred dimensions," including one with dimensions of 42 mm x 28 mm x 14 mm. (A15367-69; A11461-67.)



Part #	A	B	C
Large-15	42 mm	28 mm	15 mm
Large-13	42 mm	28 mm	14 mm
Medium-14	36 mm	24 mm	14 mm
Medium-12	36 mm	24 mm	12 mm
Small-14	33 mm	22 mm	14 mm
Small-12	33 mm	22 mm	12 mm
Small-10	33 mm	22 mm	10 mm

In addition, Dr. Brantigan inserted an implant in a patient named "JC" on July 9, 1990 to address a burst facture at the L1 vertebrae. (A15493; A11467-69, A11496-

1504; A12222-23.) The implant's dimensions were 35 mm x 24 mm x 15 mm. (*Id.*) The following post-operative CT scans, taken in 1991, show that implant: the left image is a top view of the implant (black) on the vertebrae, and the right image is a side view showing the implant with white bone growing through the holes:



(A17855, A17858; A11496-501.)

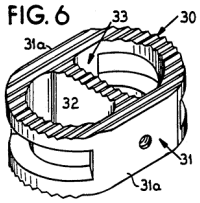
The Brantigan 42 mm and 35 mm implants meet all the structural limitations—*i.e.*, the length, width, and height requirements, and the additional details regarding the ratchetings, openings for bone growth materials, and shape—in the body of the '973 claims. (*See* Argument Section I.A, below.) They are even within the "preferred" dimensions in the '973 specification:

	'973 patent's "preferred" dimensions	**Dr. Brantigan's 42 mm implant**	**Dr. Brantigan's implant for JC**
Length (mm)	32-50	42	35
Width (mm)	24-32	28	24
Height (mm)	8-16	14	15

The inventor himself admitted the Brantigan 42 mm implant is "pretty much the same size" as his preferred embodiment. (A12138-39.)

C. The Brantigan '327 Patent Discloses Implants for Lateral Insertion With The Same Dimensions As The '973 Patent.

Dr. Brantigan obtained a 1993 patent on his commercial implants, U.S Patent 5,192,327. (A17450-59.) The '327 patent states that the implants are "suitable for anterior, posterior, or *lateral placement* in any area of the spine requiring replacement of disc or vertebral body." (*Id.* at 2:55-59, 2:64-66, 5:30-34, 6:65-67.) Figure 6 shows the implant's shape, the same as the implants in the schematics and CT scans above:



The implants are "dimensionally similar to normal vertebral bodies," (A17450 at Abstract), have "dimensions in the same ratio as normal vertebral bodies," (A17454 at 1:19-21), are "shaped to conform with the general outline perimeter of the vertebrae," (*id.* at 1:64-2:4), and are "sized to match the height of an average disc." (*Id.* at 2:19-22.) Brantigan '327 thus discloses the same dimensions claimed in the '973 patent, as construed by the district court. (A11493-95; A11719-23.)

D. The District Court Rejects Warsaw's Constructions at *Markman*.

Warsaw tried to avoid the Brantigan prior art by proposing various narrowing constructions during the *Markman* process. For example, Warsaw argued the preamble phrase "translateral spinal implant" requires that the claimed implant span "across the transverse width of the vertebrae," *i.e.*, from one edge of the apophyseal

ring (a hard, boney structure on the perimeter of each vertebrae) to the other, and that the implant's intended use (recited in the preamble) is limiting. (A1941.) Warsaw also proposed a construction of "length" that would make it depend upon the direction in which the implant was inserted in a patient. (A1946, A10798-99.) NuVasive, by contrast, argued the entire preamble was non-limiting and that "length" had its plain meaning: "the greatest dimension of the implant." (A331, A341, A2201-02.)

The district court adopted NuVasive's constructions. The court construed the preamble term "translateral spinal implant" to mean "an implant capable of translateral insertion," but concluded that the entire preamble was non-limiting because "[a] review of the '973 Patent's prosecution history demonstrates that the dimensions of the implant distinguished it from the prior art, not the inventor's intended use of the implant," and the body of the claims "fully set[s] forth the structure of the invention," *i.e.*, the implant's oversized dimensions. (A6.) With respect to "length," the court observed that "[b]oth parties offer proposed constructions," but found, consistent with NuVasive's position, that "length has a plain meaning to a person of ordinary skill in the art and does not need to be construed." (A7.)

E. The Trial: Warsaw Distinguishes the Brantigan Implants Based Solely On Its Rejected Claim Construction Positions.

With the claims requiring only an implant with specified dimensions, with the prior art Brantigan implants having those dimensions, and with the district court

having rejected Warsaw's effort to add limitations to the preamble and the term "length," one may wonder how the jury found Warsaw's claims valid. The answer: Warsaw repeated its previously rejected claim construction arguments dozens of times at trial and convinced the jury to distinguish the prior art on that erroneous basis.

1. "Translateral Spinal Implant"/"Said Implant"

Warsaw again argued that the preamble term "translateral spinal implant" imposed requirements beyond those in the body of the claim. This time, Warsaw used the court's construction of "translateral spinal implant" to argue the Brantigan implants weren't "capable of translateral insertion" because they were supposedly not "safe and effective" for lateral insertion. (A10169-170, *see also* A10121, A10156, A10170, A10198-99, A10239-40, A10288-90, A12114-15, A12119-20, A12225, A10675-80, A10780-94, A10808-10, A12181-83, A12217-18, A12243-44.)

For example, Warsaw's witnesses testified that a "translateral" implant had to be large enough to span from one edge of the apophyseal ring to the other. (A10780-82, A12181-83, A10169-70, A10177, A12139-40.) The inventor, Dr. Michelson, referred to this as a requirement the implant run "coast to coast" (from one end of the vertebrae to the other), which he supported with the same passage Warsaw had cited unsuccessfully at *Markman*. (*Compare* A1944 (citing A253 at 3:3-10), *with* A10289-90, A10169-70 (same); *see also* A10156, A10179-81, A10198-99, A10238, A10288-89.) Warsaw's witnesses also testified that a "translateral" implant had to be so large that it would be impossible to insert it from the patient's back or front. (*Id.*)

Warsaw's expert also asserted that a "translateral" implant must include structures that enable it to be laterally inserted with particular surgical tools:

> [A]nother important point are the tools that can be used to place the implant. The implant doesn't just focus and all of a sudden arrive there. It has to be placed in a safe way and tools have to be designed to provide that effective and safe approach.

(A10679-80; *see also* A10784; A12217-18; A12161-63.) And its inventor added that a "translateral" implant needed a "leading end" that "generally will be tapered or rounded or bullet shape or something that would allow the implant" to be inserted laterally. (A12139-40.)

Warsaw then used these added limitations to try to distinguish the Brantigan prior art, (*e.g.*, A12161-63, A12139-40), and told the jury in closing argument that "we have competing views on what translateral means," (A12298), and that it was for "you to decide" which view was right. (A12299-300.)

2. "Length"

Warsaw also resurrected its rejected construction of "length." The court had adopted NuVasive's proposal that "length" had its "plain meaning," *i.e.,* the greatest dimension. (A7, A341.) But Warsaw continued to use the definition it had proposed at *Markman*, which defined the implant's length by the direction of insertion:

> Q. And you have adopted a definition of "length" that is from the leading end to the trailing end of the implant, as I understand it, true?
>
> A. Yes, sir.

Q. So your definition of "length," depends on how you put the implant in the spine, right?

A. My definition of "measurement of length of the implant" depends on how it's – yes, how it's oriented.

Q. Right. So your definition is not the same as just saying the length is the longest dimension of something, right?

A. Yes.

(A10798-99.) Warsaw then distinguished the Brantigan implants by arguing their longest dimension (*e.g.*, 42 mm) was not the "length" because they were supposedly not meant to be inserted laterally. (A12141-42, A12147, A12162-63.) And Warsaw's closing argument invited the jury to apply that definition to distinguish the prior art:

> You are to decide what length means to a person of ordinary skill in the art and you remember that the issue came up about whether length means leading, the trailing edge or whether it always is the longest part regardless of what you are talking about? And there's a difference.
>
> Dr. van Dam [NuVasive's expert] testified that length is always, is always the longest part of the implant. Dr. Sachs [Warsaw's expert] said not so. To physician[s] in the industry, what we're talking about length, we're talking about leading the trailing edge. That's how we define. That's the nomenclature. Leading [to] the trailing edge. You are the fact finders and you need to sort through that.

(A12294.)

F. The Result: the Jury Upholds Validity Based on Warsaw's Erroneous Claim Construction Arguments.

NuVasive repeatedly tried to stop Warsaw from contradicting the court's construction. Before trial, NuVasive sought summary judgment by noting that Warsaw's validity arguments contradicted the construction and moved *in limine* to

prevent Warsaw from making them, but the motions were denied. (A30570-71, A30583-84, A30649-50; A30134-40, A30148-54, A30193; A30726, A31094-95; A30914; A30917.) NuVasive renewed its objections during trial, and it requested a curative instruction. (A10689-97, A11207, A31109-17, A11943-48, A12331.)

The district court gave some, but not all, of the instruction NuVasive sought. The district court's final jury instructions reiterated that "the preambles do not act as a separate limitation, and you should not consider them as a separate limitation during your deliberations," and that the word "capable" in its construction of "translateral spinal implant" "cannot be read to impose additional limitations in to the '973 patent, that are not otherwise set forth in the claim language." (A206.) But it added a further instruction at Warsaw's request, and over NuVasive's objection, that "the Court is not instructing you to ignore the claim language 'said implant,' which refers to 'translateral spinal implant.'" (*Id.*; *see also* A11947-48.) Warsaw's closing seized on this to argue that "said implant" required all the limitations that Warsaw had erroneously associated with the preamble. (A12291-92.) The jury found the '973 claims were not invalid, (A239), and the court denied NuVasive's post-trial motions. (A42, A30257-58.)

III. Warsaw's '933 Patent.

A. The '933 Patent Claims a Two-Blade Retractor in Which "Each" Blade Laterally Moves and Pivots.

Warsaw's '933 patent relates to a retractor that includes two blades—called a "first portion" and a "second portion"—that together form a "working channel"

through which a surgeon can access the disc. (A260-78.) When a surgeon inserts the retractor into a patient, the channel is "enclosed" by the two blades, such that their edges touch, with no gaps between them. (*See, e.g.*, A269-71 at 2:51-3:32; A17-18.)

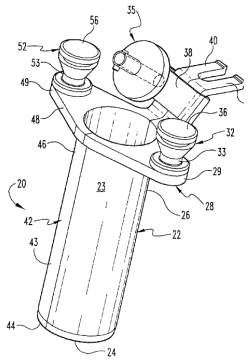


Fig. 3

After insertion, the surgeon can enlarge the channel by laterally moving and pivoting each blade, as shown in Figure 13. (A271-73 at 6:21-58, 10:15-30.)

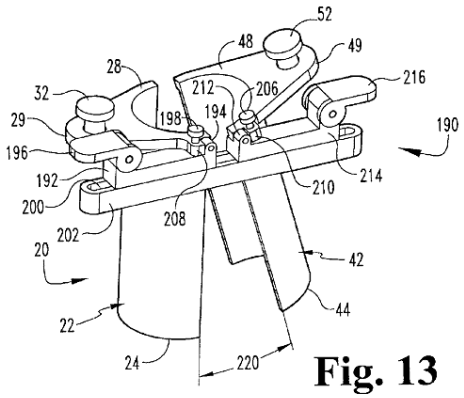


Fig. 13

Warsaw distinguished its claimed two-blade retractor because "each" blade laterally moved and pivoted. (A2101-02.) In particular, Warsaw overcame a rejection over a prior art two-blade retractor in which both blades could pivot, but only one could move laterally, by arguing that the prior art "fails to disclose a retractor in which *each* of the blades are laterally moveable away from one another." (A2102.)

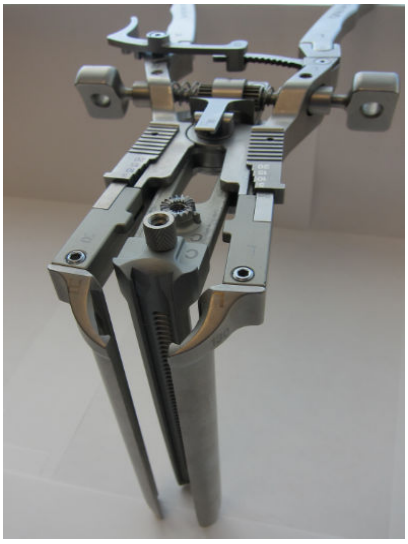
Warsaw asserted dependent claims 21, 57, and 66, which cover, respectively, a retractor, a surgical kit that includes the retractor, and a surgical method using the retractor. All claims, as construed, require a retractor with a working channel that is (1) completely enclosed by two blades, and (2) enlargeable by laterally moving and pivoting "each" of those "said" blades. (A17-18.) Claim 1 (from which claim 21 depends) is representative and includes those requirements as shown below:

> 1. A tissue retractor for percutaneous surgery in a patient, comprising:
>
> a first portion having a proximal end and a distal end; and
>
> a second portion having a proximal end and a distal end,
>
> said second portion forming with said first portion a working channel in communication with an exterior of said first and second portions at said proximal ends and said distal ends with ***said working channel being enclosed by said first portion and said second portion*** between said distal and proximal ends,
>
> wherein ***said working channel*** is enlargeable by laterally moving ***each*** of ***said first and second portions*** away from one another and pivoting ***each*** of ***said*** distal ends of ***said first and second portions*** away from one another such that only a portion of said working channel is enclosed by said first and second portions.

(A275 at 13:33-48.)

B. NuVasive's Products Are Three-Blade Retractors in Which One Blade Does Not Laterally Move and Pivot.

NuVasive's accused MaXcess II and MaXcess III retractors have three blades that form a working channel; it is undisputed that no two blades "enclose" the working channel, as shown in the photograph of the MaXcess II below. (A10770-72.)



It is also undisputed that only two blades can laterally move and pivot. (A10773-74; A11756-57.) The center blade stays stationary to separate the patient's nerves from the surgeon's instruments, and, in some cases, to serve as a dock for NuVasive's nerve-monitoring technology. (A10774; A11256-58; A11416-17; A11752-57.)

C. Warsaw's Infringement Case under the Doctrine of Equivalents.

Warsaw saw problems in the fact that the '933 patent discloses exclusively two-blade retractors, while NuVasive's accused products are three-blade retractors. Warsaw's expert acknowledged NuVasive's retractors do not literally meet the claim requirement of "said working channel being enclosed by said first portion and said second portion" because no two blades enclose the channel. (A10728-29.) So Warsaw argued that all three NuVasive blades satisfied this limitation under the doctrine of equivalents, (A10729-34), even though this would vitiate the claim's explicit numerical requirement that two blades enclose the channel. But then, when addressing the second part of the claim—which requires that "said" working channel

be enlargeable by laterally moving and pivoting "each" of "said first and second portions"—Warsaw's expert took a different position on what the "first and second portions" were, identifying only two of NuVasive's three blades. (A10737-43, A10807-08.) The jury found infringement based on this legally erroneous theory, (A240), and the district court denied JMOL. (A42.)

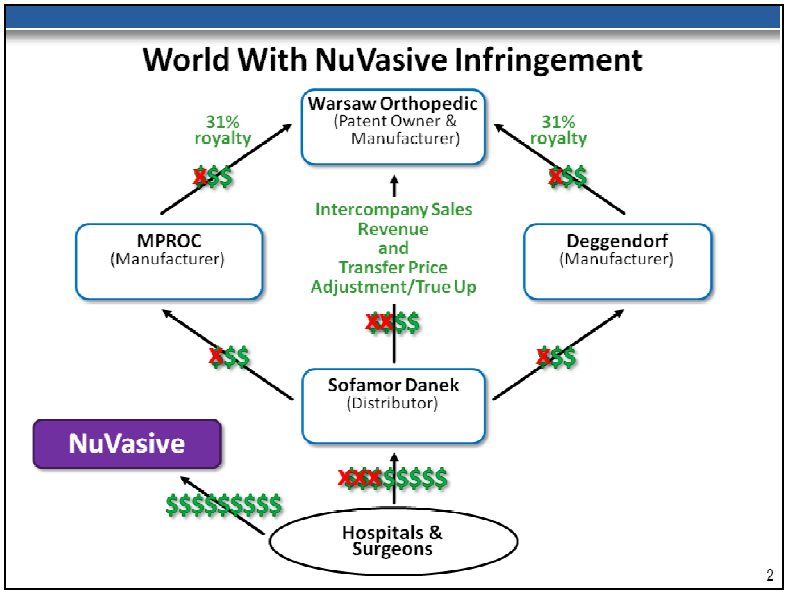
IV. Warsaw's Damages Presentation, and the Jury's Award.

If liability on either Warsaw patent is affirmed, this appeal also challenges two legally erroneous aspects of Warsaw's "lost profits" award—(1) Warsaw's claim to funds transferred to it by other Medtronic entities and (2) its claim to "profits" on unpatented items sold with the accused products.

A. Warsaw's "Lost Profits" Were Funds That Supposedly Would Have Been Transferred to It by Other Medtronic Entities.

Warsaw, the patent owner, does not sell to outside customers any of the products for which it sought "lost profits" damages. (A10907-09; A11097.) Instead, a separate Medtronic entity makes the implants (Medtronic Sofamor Danek Deggendorf GmbH), an unrelated third-party makes the retractors, and a separate Medtronic entity (Medtronic Sofamor Danek USA, Inc. (MSD)) sells everything to hospitals and surgeons. (A10889-90, A10907-08, A11096-97; A16956.) These separate entities transfer money to Warsaw, and Warsaw's "lost profits" claim was based solely on those transfers. (A11010-11, A11035-36, A10972-75.)

In particular, Warsaw's trial demonstrative shows that it sought to recover three streams of revenue: (1) lost transfer payments from MSD to Warsaw for products shipped to MSD; (2) a lost "true up payment" from MSD to Warsaw under a policy established by their parent (Medtronic, Inc.) for tax purposes; and (3) "lost royalties" that Warsaw would have received from Medtronic manufacturing entities:



(A10972-95, A11010-11, A11035-36 (Warsaw's expert explaining his calculations); *see also* A10923-36; A23538-48; A23549-55); A10891-95; A20626-35; A25405-13; A25422-28; A25429-35 (Warsaw's evidence explaining the various transfers).)

B. Most Warsaw "Lost Profits" Were From Unpatented Products.

Warsaw calculated the alleged amount of those three sources of lost revenue by including not only the additional implants and retractors that MSD would supposedly have sold, but also revenue from unpatented items that could be used with them. (A10998-A11000, A11080-81.) For example, Warsaw sought damages on unpatented

"fixation" systems and "biologics." (*Id.*) Both fixation and biologics can be and are used separately from the accused implants and retractors. (A11119-22, A11186-87, A11991-92, A12020-21, A12058-59; A10617, A11803.) Fixation includes rods and screws to help stabilize the spine. (*Id.*) Sometimes fixation is not used at all, and often it is installed in a later stage in the surgery or on a different day. (*Id.*) Biologics promote post-surgical bone growth. (*Id.*) A surgeon can use one company's implants and retractors, but a different company's fixation and biologics—in fact, about half of NuVasive XLIFs were performed with Medtronic biologics or fixation. (*Id.*)

Warsaw's damages calculation for the '973 patent is representative. Warsaw's expert opined that MSD would have sold implants, retractors, and other unpatented components related to one of four Medtronic surgical procedures—DLIF, ALIF, TLIF, or PLIF—for each NuVasive XLIF procedure that had used an accused implant and retractor. (A10975-A11010.) He proposed two alternative approaches: the "multi-procedure" market, where each NuVasive XLIF would be replaced by one of the four MSD-related surgeries; or the "two-procedure" market where each XLIF would be replaced by a DLIF. (A10987-89.) Warsaw's expert then tried to ascertain MSD's average "lost revenue" for each lost procedure by estimating how frequently each unpatented item was used, and number of each procedure MSD supposedly lost. (A10997-1008, A11049-54, A11111-18, A24925-26.) Finally, he calculated Warsaw's "lost profits" by determining how much it would have received for those procedures from MSD and the other Medtronic entities. (A11010-11, A11052-54.)

The inclusion of unpatented items greatly inflated Warsaw's lost profits demands. For example, in the "multi-procedure" scenario, over 98% of the "lost procedures" would have been an ALIF, PLIF, or TLIF, and, for each of those, most of the lost revenue was from unpatented fixation (56-57%) and biologics (5-9%). (A11990-92; A30455; A11006-08; A24892; A24898; A24903.)

The jury awarded damages of $101,196,000 for "lost profits damages (with royalty remainder)" for Warsaw's '973, '933, and '586 patents, and further stated that it used royalty rates of 10%, 3%, and 2%, respectively, for sales not subject to lost profits, in calculating that total. (A241-42.) The jury provided no other information regarding how it arrived at the lump sum. The parties subsequently settled the dispute on the '586 patent, so it is not part of the appeal.

V. Warsaw's Appeal of Post-Trial Damages-Related Rulings.

If liability on either Warsaw patent is affirmed, the Court will also have to consider Warsaw's appeal regarding ongoing royalties and supplemental damages.

A. Ongoing Royalties.

The court adopted ongoing royalty rates higher than the jury's rates for pre-verdict damages—13.75% for the '973 and 8.25% for the '933. (A66-74.) It calculated them by taking the rates that Warsaw had argued at trial would have made it "willing to forego its own sales" (25% and 15%, respectively), then adjusting downward to reflect the jury's implicit finding that Warsaw's lost profits were only 55% of what Warsaw had argued. (A72-74.) The court thus compensated Warsaw

for potential future lost profits while recognizing that "the profits Warsaw forfeits by allowing NuVasive to compete are substantially less than the amounts Warsaw proposed at trial." (A73.) The court added that, in the "particular circumstances" here, it was "not inclined to view the defendant's continued presence in the market as an act of willful infringement" because "the trial judge concluded that it was in the public interest to allow defendant to remain in the market and pay an appropriate royalty to do so." (A72; *see also* A30260.) It subsequently denied Warsaw's motion to reconsider the base for the '933 royalty, refusing to permit royalties on unpatented components or on implants already subject to royalties on the '973. (A75-77.)

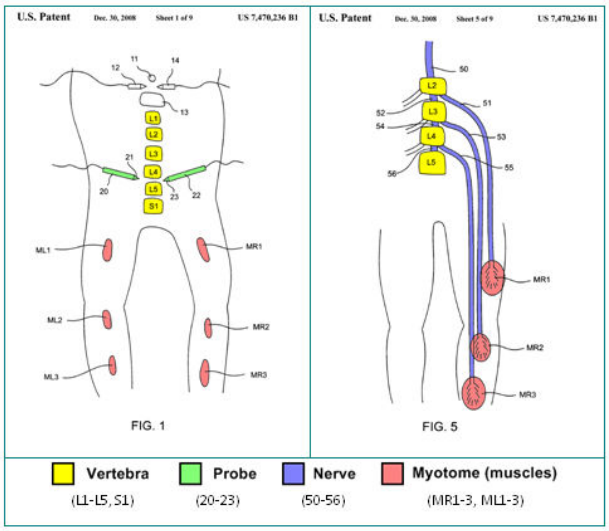
B. Supplemental Damages.

Warsaw did not take a clear position at trial regarding the period for which it sought damages. Its expert relied on financial data ending before trial. But the jury instructions and verdict form imposed no limit on the period for which the jury could impose damages, (A221-23, A228), and Warsaw's expert encouraged them to increase damages to account for the period for which Warsaw had not required financial data. (A11012-13.) After the jury awarded Warsaw less than it sought, Warsaw moved for supplemental damages. The court correctly denied this motion, explaining that this "would be an improper invasion of the providence of the jury," which may have included these damages, and that "absent critical information about the jury's calculations, the court would really be unable to formulate a supplemental damages award" consistent with the verdict. (A30259.)

VI. NuVasive's '236 Patent.

A. NuVasive's Nerve-Monitoring Creates a Safe and Reproducible Lateral Procedure.

NuVasive's U.S. Patent 7,470,236 covers NuVasive's early nerve-monitoring technology. (A279-300; A10467-70.) The '236 patent disclosed a method, shown in Figures 1 and 5, in which a surgeon laterally inserts a probe that emits a stimulus signal and simultaneously monitors a patient's leg muscles for a response. (*Id.*)



The system automatically and incrementally increases the signal's intensity in a step-by-step "staircase" fashion, until it detects a predetermined level of muscular response. (A294-98 at 5:38-61, 12:52-59, 13:65-14:13.) The surgeon can determine the distance between the probe and a nerve based on the signal intensity that elicits a response—the closer the nerve, the lower the intensity needed to elicit a response. (*Id.*) Once the system detects a response, it immediately stops that signal to avoid over-stimulating the nerve. (A294-300 at 5:46-50, 17:56-60.) But the stoppage is not

permanent: a surgeon can rapidly repeat these steps (by starting a new signal) to obtain continuous guidance as the probe moves toward the spine. (A299 at 16:10-22.)

Asserted claims 1, 5, and 9 reflect these aspects of the invention. Claim 1 is a method of using nerve-monitoring during lateral spinal surgery, with the steps of:

> (a) emitting a stimulus signal from a probe that is "introduced toward a lateral aspect" of a vertebrae in the lumbar or thoracic spine,
>
> (b) monitoring muscles coupled to a spinal nerve to see if the signal elicits a predetermined neuromuscular response
>
> (c) increasing the signal's intensity until it elicits the predetermined neuromuscular, and then "stopping the emission of said stimulus signal immediately after" detecting that response, and
>
> (d) notifying the operator of the signal's intensity when it triggered the response, where the intensity level represents to probe's proximity to the nerve.

(A300; A11299-302.) Claims 5 and 9 require repeating this method and either varying the signal's intensity or automatically repeating the sequence. (*Id.*)

B. Medtronic's Infringing NIM-Eclipse System.

Medtronic sells the NIM-Eclipse device and instructs surgeons to use its "Nerve Proximity Mode" to laterally access a patient's vertebrae through the psoas while avoiding contact with nerves. (*See, e.g.*, A11278-95; A16348-50; A17922-23; A17903; A16261; A17956-65.) The surgeon laterally inserts a probe that automatically stimulates the nerves, and NIM-Eclipse measures the signal intensity needed to elicit a predetermined muscular response and displays that number to the surgeon. (A11284-85, A11292-93.) Medtronic instructs surgeons that they should redirect their

instruments if it falls below 8 mA. (*Id.*) NIM-Eclipse also notifies the surgeon that he or she is approaching a nerve by playing an audio tone that increases in frequency as the surgeon approaches a nerve. (A11286.) NuVasive's expert, Dr. Stephen Raymond, testified that use of NIM-Eclipse in Medtronic's DLIF meets each step of the asserted claims, and that Medtronic instructs surgeons to use NIM-Eclipse this way. (A11287-305.) Medtronic called no rebuttal witnesses.

Instead, Medtronic's non-infringement position focused only on the "stopping" step. It had argued at claim construction that "stopping" required *permanent* cessation of the stimulus signal. (A1871-72.) The district court correctly rejected that construction, (A22), which was inconsistent with dependent claims that require automatically repeating the method. Applying the court's construction, Dr. Raymond testified that use of Nerve Proximity Mode met the "stopping" step because NIM-Eclipse repeatedly emits a stimulus signal that increases in intensity until a response is elicited, then stops that stimulus signal, and communicates information about nerve proximity to the user. (A11309-11.) When NIM-Eclipse repeats this process, each iteration begins a new stimulus signal. (A11312.)

The jury, crediting that testimony, found that Medtronic induced and contributed to infringement of claims 1, 5, and 9, and awarded $660,000. (A240-42.) The district court denied Medtronic's post-trial motions, (A42, A30257), and imposed a 5.5% ongoing royalty, the jury's rate for pre-verdict infringement. (A74).

SUMMARY OF THE ARGUMENT

'973 Patent—Anticipation and Obviousness. Warsaw put on no evidence that the Brantigan prior art lacks any feature of the '973 claims under the court's claim constructions, but instead relied on additional limitations—*e.g.,* that the implant span from "coast-to-coast," work with tools, and have a "length" that depended on the insertion direction. That is not substantial evidence sufficient to support the verdict.

'973 Patent—Indefiniteness. If the Court reaches this issue, it should conclude the claims are indefinite under *IPXL*. The inventor claimed his implant not by reciting a range of numerical dimensions, but by reciting its dimensions relative to "the vertebrae" between which it is inserted. In doing so, he introduced a method step into his apparatus claims—selecting a particular patient and part of the spine to insert the implant.

'933 Patent. Warsaw cannot legally stretch two-blade claims, in which "each" blade must be able to laterally move and pivot, to cover NuVasive's products, which are three-blade retractors in which not "each" blade can laterally move and pivot. Warsaw's equivalents theory is barred as a matter of law because (1) it vitiates the requirement that a specific structure (two blades) enclose the working channel, and (2) it is inconsistent with the claim language requiring that the same set of blades both enclose the working channel and "each" laterally move and pivot.

"Lost Profits." If the Court reaches this issue, Warsaw cannot recover any lost profits because it does not sell products to outside customers; it should not be

permitted to create a "lost profits" claim by contracting with separate Medtronic entities. Moreover, even if Warsaw could claim some lost profits, over half the lost profits it sought were on unpatented products with no functional relationship to the patents because they work equally well with any company's implants and retractors and can be installed separately or not at all.

Supplemental Damages. If the Court reaches this issue, it should affirm. Warsaw encouraged the jury to award damages for the "gap" period, the instructions did not prevent the jury from doing so, and it is unclear what the jury actually did. Given the risk of double-counting, and given that Warsaw did not explicitly reserve its rights to separately address the issue after trial, the district court did not abuse its discretion in denying supplemental damages.

Ongoing Royalty. If the Court reaches this issue, it should find the district court did not abuse its discretion in choosing a rate higher than the jury's but lower than Warsaw's demand. The district court properly started with a rate that Warsaw said would compensate it for competition between separate Medtronic entities and NuVasive, and then adjusted it based on factors unique to this case—the jury's lost profits finding and the public interest in the continuing use of NuVasive's XLIF.

'236 Patent. The district court correctly construed the claims consistent with the intrinsic evidence, and substantial evidence supported the jury's infringement findings under that construction. Warsaw's disclaimer arguments were refuted by the very person (Dr. Raymond) whose prior art prompted the supposed disclaimer.

ARGUMENT

I. The Judgment on the '973 Patent Should be Reversed or Vacated Based on Anticipation and Obviousness.

The Court should determine as a matter of law that the '973 claims are anticipated or obvious, or, at a minimum, vacate and remand for a new trial. The "validity analysis is a two-step procedure: The first step involves the proper interpretation of the claims. The second step involves determining whether the limitations of the claims as properly interpreted are met by the prior art." *TI Group Auto. Sys., Inc. v. VDO North Am., L.L.C.*, 375 F.3d 1126, 1139 (Fed. Cir. 2004). The district court correctly construed the claims, and there is no genuine dispute the claims are invalid under that construction.

A. The Brantigan Implants Anticipate the Asserted Claims.

This Court reviews a denial of JMOL *de novo* under Ninth Circuit precedent. *See Janes v. Wal–Mart Stores Inc.,* 279 F.3d 883, 886 (9th Cir. 2002). Anticipation is a question of fact reviewed for substantial evidence. *Orion IP, LLC v. Hyundai Motor America*, 605 F.3d 967, 974 (Fed. Cir. 2010). "To anticipate a claim, a single prior art reference must expressly or inherently disclose each claim limitation." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009). Where, as here, there are no "genuine factual disputes underlying the anticipation inquiry, the issue is ripe for judgment as a matter of law." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005). The district court erred in not granting JMOL.

1. The Brantigan Implants Have the Same Dimensions and Structural Characteristics Required by the Asserted Claims.

Each asserted '973 claim recites a spinal implant with certain dimensions dictated by the size of the vertebrae where the implant is to be inserted. Other than those dimension-based limitations (and some further structural requirements in certain dependent claims), these apparatus claims state no additional limitations. When compared to the average human vertebral dimensions, Dr. Brantigan's prior art implants are of the size required by each asserted claim. That establishes anticipation.

Claim 1. Each asserted claim depends from or otherwise possesses the dimensional limitations recited in claim 1. Claim 1 has the non-limiting preamble and three structural limitations that recite the dimensions of the claimed implant relative to where and in whom it is inserted: "said implant [1] having a length that is greater than one half the transverse width of the vertebrae, [2] said length being substantially greater than the depth of the vertebrae, and [3] a height for contacting each of the two adjacent vertebrae." (A257 at 11:23-27). The Brantigan implants satisfy these limitations because it is undisputed that they have the following dimensions:

BRANTIGAN 42 MM IMPLANT	
Length	42 mm
Width	28 mm
Height	14 mm

BRANTIGAN IMPLANT FOR JC	
Length	35 mm
Width	24 mm
Height	15 mm

(A15367-69; A11480-81; A11499; A15359; A12222-23.)

As to the first two limitations—"having a length that is greater than one half the transverse width of the vertebrae" and "said length being substantially greater than the depth of the vertebrae" —the Brantigan implants have lengths of 42 mm and 35 mm. Based on the stipulated average dimensions of the vertebrae in an adult human (shown below), each Brantigan implant meets both these limitations.

For example, the 42 mm Brantigan implant has a length greater than 22.6 mm, which is "one half the transverse width" of the average L1 vertebrae:

	T2	**T7**	**T12**	**L1**	**L2**	**L3**	**L4**	**L5**
Transverse width (mm)	29.8	31.0	43.8	45.2	47.7	49.6	51.2	53.4
"one half the transverse width" (mm)	14.9	15.5	21.9	22.6	23.9	24.8	25.6	26.7
"depth of the vertebrae" (mm)	18.1	27.0	31.7	31.9	33.3	33.9	34.9	35.1

(A17071-76; A18874; A11706-09.) The same 42 mm Brantigan implant also has a "length being substantially greater than the depth" of the L1 vertebrae, which is 31.9 mm deep. (*See, e.g.*, A11708-09 (implant length of 35 mm is substantially greater than vertebrae depth of 30 mm); A10704 (Warsaw's witness testifying that the lengths of NuVasive's CoRoent XL implants—40, 45 and 50 mm—are all substantially greater than the depth of "the vertebrae").) Indeed, based on these stipulated average measurements, the 42 mm Brantigan implant meets both limitations with respect to vertebrae T2 through L5, and the 35 mm Brantigan implant meets both limitations with respect to T2 through L3.

The Brantigan implants also meet the third limitation, having "a height for contacting each of the two adjacent vertebrae." Warsaw's expert testified that any implant having a height from 5-16 mm satisfies this limitation. (*See, e.g.*, A10665, A10705 (all CoRoent XL implants satisfy the height limitation); A24679-80 (CoRoent XL implants have heights ranging from 5 mm to 16 mm).) The Brantigan implants, which have a height of 14 mm and 15 mm, respectively, fall within that range too. (A11492-93, A11502; A11709.) The Brantigan prior art implants thus satisfy the dimensional limitations common to all the claims.

Indeed, as explained above, the Brantigan implants fall within the '973 patent's preferred embodiment. (*Compare* A15367-69, A11480-81, A11499 *with* A256 at 10:42-47.) This further demonstrates that the Brantigan implants satisfy these dimensional limitations—otherwise, the claims would exclude the preferred embodiment, a result disfavored under this Court's precedent and never suggested by Warsaw.

Claim 24. Claim 24 adds to claim 1 that the implant is "for use in the lumbar spine in which the length of said implant is in the range of approximately 35 mm to 50 mm." (A257 at 12:22-24.) The lengths of both Brantigan implants (42 mm and 35 mm) fall within that range. (A15493; A11467-69, A11496-504; A11711.) The phrase "for use in the lumbar spine" adds no limitation to the claim; it simply states an intended use. *Marrin v. Griffin*, 599 F.3d 1290, 1293-94 (Fed. Cir. 2010). But even if the term was limiting, it is undisputed that both Brantigan implants were capable of use in the lumbar spine. (A11528; A12167-68; A18869.)

Claims 41 and 42. Claims 41 and 42 add to claim 1 (via claims 35 and 40), the features: (a) that the implant has "a width that is at least as great as the height," (b) "said implant has surface roughenings for engaging said two adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of exterior of said implant," (c) "said surface roughenings include a plurality of ratchetings," and (d) "said ratchetings face one direction." (A258 at 13:1-25.) The Brantigan implants meet each of these requirements because (a) they have widths (28 mm and 24 mm) that are greater than their heights (14 mm and 15 mm), (b) it was undisputed they have exterior roughenings for engaging adjacent vertebrae and maintaining the implants in place, (A15359-61; A15369; A11465-66; A11703-04, A11711-12), (c) it was undisputed that the Brantigan roughenings are ratchetings, (*id.*), and (d) it was undisputed that the Brantigan ratchetings all face in one direction. (*Id.*)

Claim 57. Claim 57 adds to claim 35 the limitation that "said implant is generally rectangular in shape"—a limitation that NuVasive showed and Warsaw does not dispute. (A11712; A15359-61; A15369; A15358.)

Claim 61. Claim 61 adds to claim 1 the requirement that the implant include openings capable of retaining bone-growth promoting substances:

> said implant having an outer surface with a plurality of openings passing through said implant, said plurality of openings capable of retaining fusion promoting substances and capable of permitting bone grown in continuity from one of said adjacent vertebrae to the other of said two adjacent vertebrae to permit fusion of said two adjacent vertebrae to occur at least in part through said implants capable of engaging both of said vertebrae.

(A258 at 14:24-31.) The Brantigan implants meet this additional limitation: they have two inner openings that were capable of retaining—and were used to retain—fusion-promoting bone graft material. (A15359-61; A15362-69; A11483-84; A11489; A11697-98, A11712-13, A12228-29; A18868, A18874; A17863.) Bone graft material, in turn, was actually used for fusing adjacent vertebrae. (*Id.*) The uncontroverted evidence therefore demonstrated that the Brantigan prior art implants anticipate the asserted claims as a matter of law under the district court's claim constructions.

2. Warsaw's Validity Arguments Pertained Only to Features That Were Not Part of the Claim Construction.

Warsaw's sole substantive response was to rely on distinctions that are not properly part of the claims. That is inadequate as a matter of law. *See, e.g.*, *Soverain Software LLC, v. Newegg, Inc.*, 705 F.3d 1333, 1339-40 (Fed. Cir. 2013) (reversing a denial of JMOL of invalidity where the patentee's only attempt to show certain elements were absent from the prior art was based on limitations "not embodied in the claims and not reflected in the claim construction"); *Orion IP*, 605 F.3d 967, 975-77 (Fed. Cir. 2010) (reversing denial of JMOL of anticipation because the only basis for the jury's non-anticipation ruling was the patentee's argument and evidence regarding features not required by the asserted claims); *Marrin*, 599 F.3d at 1294-96 (affirming summary judgment of anticipation where patentee's arguments related mostly to the claims' non-limiting preamble).

First, Warsaw said the Brantigan implants did not anticipate by arguing they were not "capable of" translateral insertion because (a) they did not span "coast-to-coast" from one end of the apophyseal ring to the other, (b) supposedly could not work with certain insertion tools, and (c) did not have ridges facing the "correct" direction. (A12139-42, A12145-48, A12162-63; A30946-47.) But that evidence is irrelevant because the district court determined that "the preambles" are "not limiting" and "the term 'capable' cannot be read to impose additional limitations in the '973 Patent, that are not otherwise set forth in the claim language." (A206.)

It will be no answer for Warsaw to reargue that construction on appeal. The preamble could not limit the claims to an implant that works with insertion tools because that would render superfluous dependent claims 10 and 47, which add the requirement of "an engagement means for engaging instrumentation for the insertion of said implant." (A257-58 at 11:48-50, 13:35-37.) Likewise, the preamble could not require an implant with a length that spans "coast-to-coast" across the full transverse width of the vertebrae because it would render superfluous the limitation in the body of an implant with "a length that is greater than one half the transverse width of the vertebrae."

Second, Warsaw's argument the Brantigan implants lacked the "length" limitations was based on the erroneous assumption that "length refers to the distance measured from the insertion to the trailing end.'" (A12162-63; A30947-48.) The district court rejected this construction by adopting NuVasive's construction that

length has its "plain meaning," namely, the greatest dimension. (A7.) And with good reason—the dictionary definitions presented to the district court all defined the length as the greatest dimension, (A31081-83; A31085-87; A2057), and the exemplary implants in the '973 specification also identify the longest dimension as the length. (A254-56 at 6:38-57, 10:41-46, 7:21-28.) Moreover, Warsaw's expert admitted that Warsaw's construction would make the implant's "length" change depending on how it is inserted. (A10798-99.) That cannot be right, particularly in claims that do not require actual insertion. Therefore, Warsaw's evidence under its contrary, rejected claim construction is all irrelevant.

Finally, Warsaw pointed to evidence supposedly showing that the Brantigan implants had not actually been inserted laterally into a patient. (A12298-303.) But whatever "capable of" means here—and the district court correctly instructed that it imposed no limitations beyond those in the body of the claims—it cannot mean actual use and insertion. *Cf. Fantasy Sports Props. v. Sportsline.com*, 287 F.3d 1108, 1118 (Fed. Cir. 2002) (software was "capable of" performing the claim limitations "regardless [of] whether that means is activated or utilized in any way"). So it is irrelevant whether the Brantigan implants actually were inserted laterally. *Catalina*, 289 F.3d at 809 ("[T]he patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure.").

The bottom line is that Warsaw's validity arguments were all irrelevant under the district court's (correct) constructions. The Brantigan implants anticipate because

they have the same "oversized" dimensions recited in the body of the claims, have the additional limitations in the dependent claims, and fall squarely within the '973 preferred embodiment.

B. Brantigan '327 Invalidates the Asserted Claims.

1. Brantigan '327 Discloses All the Dimensional Limitations of the Claims and Renders Obvious the "Ratchet" Limitations.

Under the district court's claim construction, the Brantigan '327 patent anticipates claims 24, 57, and 61, and renders obvious claims 41 and 42, as a matter of law. The analysis is similar to the discussion of the commercial Brantigan implants.

Claims 1 and 35. Brantigan '327 discloses the dimensional limitations of claims 1 and 35 because it describes an implant that is "shaped to conform with the general outline perimeter of the vertebrae," is "dimensionally similar to normal vertebral bodies," has "dimensions in the same ratio as normal vertebral bodies," and is "sized to match the height of an average disc." (A17450-59 at Figs. 10-11, 13-14, Abstract, 1:19-21, 1:54-2:4, 2:19-22, 4:5-8, 7:29-34; A11493-97, A11719-25; A18867.) Such an implant would necessarily have (1) a length greater than half the transverse-width of the vertebrae, (2) a length substantially greater than the depth of the vertebrae, (3) a height for contacting each of the two adjacent vertebrae, and (4) a width that is at least as great as the height, as claimed. (A11719-22; A11493-97.)

Claim 24. NuVasive's expert testified, without contradiction, that Brantigan '327 inherently discloses an implant length between 35-50 mm, under the district

court's construction of "length," based on Figure 10 and the skilled artisan's knowledge of average vertebral size. (A11722, A11725, A17452; A17071-76.)

Claim 57. Warsaw admitted that Brantigan '327 teaches an implant generally rectangular in shape. (A11712, A11726.)

Claim 61. Brantigan '327 teaches the dimensional limitations of this claim for the same reasons given for claim 1. In addition, it was undisputed the '327 patent teaches openings used to retain fusion promoting substances, as claimed. (A18874; A17456 at 6:37-40; A11489; A11726.) Thus, claims 24, 57, and 61 are anticipated as a matter of law.

Claims 41 and 42. The only additional features of claims 41 and 42 are that the implant must include surface roughenings—which Warsaw admits are disclosed in Brantigan '327 (A18868)—that are angled ratchetings (claim 41) and all face one direction (claim 42). An earlier Brantigan patent, the '757, discloses ratchetings facing one direction, which was a well-known feature of the prior art. (A18875; A17442-49 at Fig. 7; A11722-26, A12227.) It would have been obvious to incorporate the ratchetings from the earlier '757 design into the Brantigan '327 implant. (*Id.*) And, in fact, Dr. Brantigan did so in the design of his commercial implants. (A15359-61, A15369.) These claims are thus obvious as a matter of law. *Boston Sci. Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 990-92 (Fed. Cir. 2009).

2. Warsaw's Arguments Are Irrelevant Under the Correct Construction.

Here again, Warsaw distinguished Brantigan '327 based only on features that are not in the claims, *i.e.*, (1) the location of the implant's tool holes, (2) the fact it supposedly did not span from "coast-to-coast" because it was not designed to sit on the apophyseal ring, (3) the direction of the ratchetings, and (4) that certain embodiments were small enough to be inserted from the patient's front or back. (A12159-65, A12139-48; A30945-46.) Just as these points were irrelevant distinctions over the Brantigan commercial prior art, they are irrelevant distinctions over the Brantigan '327 patent. Moreover, Brantigan '327 states that its implants are "suitable for anterior, posterior, or ***lateral*** placement in any area of the spine requiring replacement of disc or vertebral body." (A17450-59 at 2:55-59; *see also* 2:64-66, 5:30-34, 6:65-67.) So Warsaw's arguments that they were not "capable of" lateral insertion are untenable under any understanding of the court's construction.

C. At a Minimum, a Remand is Necessary to Determine Validity Without Warsaw's Improper Claim Construction Arguments.

This Court has held repeatedly that "it is improper to argue claim construction to the jury because the risk of confusing the jury is high when experts opine on claim construction." *See, e.g., Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1337 (Fed. Cir. 2009). Yet Warsaw's witnesses contradicted the district court's claim construction dozens of times, and its lawyer argued during closing that NuVasive and Warsaw "have competing views on what 'translateral' means" and "it's for you to

decide," (A12298-99), and that "you are to decide what length means to a person of ordinary skill in the art." (A12294.) It is impossible to know which of these improper arguments led the jury astray. What we do know is each was independently prejudicial because Warsaw erroneously used each to distinguish the prior art. Therefore, if the Court finds any of Warsaw's arguments were erroneous, it should, at a minimum, vacate and remand for re-determination without Warsaw's improper argument.

II. Even if the Asserted '973 Claims Are Not Invalid In Light of the Prior Art, They Are Indefinite.

Each asserted claim of the '973 patent is invalid as indefinite under 35 U.S.C. § 112(b). "It has long been understood that a patent must describe the exact scope of an invention." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996). "The statutory requirement of particularity and distinctness in claims is met only when they clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise. A zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field." *United Carbon Co. v. Bitney & Smith Co.*, 317 U.S. 228, 236 (1942). The claims here are indefinite because they purport to cover an apparatus, yet the skilled artisan cannot determine if they cover a given implant without reference to a particular use.

The indefiniteness problem arises from how the claims describe the implant's dimensions. The claims recite the implant's length and height relative to the

dimensions of "the vertebrae" between which it is inserted. (A257-58 at 11:21-27, 13:1-7, 14:18-31.) This implicitly requires the skilled artisan to select a particular use for an implant—*i.e.*, insertion into a particular patient, between two particular vertebral levels—before it is possible to know whether that implant is covered by the claims. Indeed, Warsaw acknowledged as much in its claim construction briefing below: "[p]ersons of ordinary skill in the art would understand how to select an implant with a length greater than one half the transverse width of the vertebrae *upon selection of the vertebrae for implantation*." (A1946 (emphasis added).) And the inventor, in resisting an indefiniteness rejection during prosecution, argued that "*[t]he occasion of the use of the implant* allows for the desired measuring and determination of the appropriate size implant." (A31039 (emphasis added).)

The claims thus leave it unclear whether infringement occurs the instant an implant is made, or instead occurs only after a surgeon selects the implant for a particular use with a particular patient. That renders them indefinite as a matter of law. *See, e.g., IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1383-84 (Fed. Cir. 2005) (invalidating a system claim that included a limitation requiring a user to actually use a component of the system); *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003) (rejecting a construction that would mean a particular composition "might infringe or not depending on its usage in changing circumstances" because "that is the epitome of indefiniteness"); *Paragon Solutions, LLC v. Timex Corp.*, 566 F.3d 1075, 1090-91 (Fed. Cir. 2009) (same, for an apparatus claim).

No case holds that it is permissible to write an apparatus claim where coverage cannot be determined until one selects a particular use. The district court relied on *Howmedica Osteonics Corp. v. Tranquil Prospects, Ltd.*, 401 F.3d 1367 (Fed. Cir. 2005), but that case relates to whether the claimed "transverse sectional dimensions" were plainly identified with a place to take the measurements, not with whether the measurements could not be known until the device was used. *Id.* at 1371-73. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565 (Fed. Cir. 1986), also cited below, is likewise inapplicable. The claim there addressed a wheelchair "so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats thereof," and the court emphasized that the parties had agreed that, under the claims, one "must measure the space between the selected automobile's doorframe and its seat and then dimension the front legs of the travel chair so they will fit in that particular space in that particular automobile." *Id.* at 1576. The court thus never considered whether the claims were indefinite as a mixed apparatus-method claim, making it inapplicable here. *Cable Television Assoc., Inc. v. Am. Cinema Editors, Inc.*, 937 F.2d 1572, 1581 (Fed. Cir. 1991) ("When an issue is not argued or is ignored in a decision, such decision is not precedent to be followed in a subsequent case in which the issue arises."). Actual use of the wheelchair was unnecessary to determine the scope of the claims there, because the wheelchair needed only to fit in "an automobile"—that is, some existing automobile. By contrast, actual use of an implant is necessary to determine the scope of the claims of the '973 patent, because its

dimensions must be compared to those of "the vertebrae"—that is, the particular vertebrae between which the implant is inserted.

It is thus impossible to discern the precise boundaries of the '973 claims, and they are invalid for indefiniteness. The power of apparatus claims is that they provide coverage independent of ultimate use, but the price to be paid is that they must be written to provide coverage independent of ultimate use. The applicant might have avoided this result by claiming a method of using the implant, although one of his related patents (No. 5,772,661), which did attempt to do so, was ultimately abandoned during reissue proceedings after the PTO rejected it over prior art. Or the applicant might have written an apparatus claim that specified the implant's dimensions in numerical ranges (like he did in the specification for the preferred embodiment). (A255-56.) But, by tying the scope of these apparatus claims to the implant's use, the applicant rendered them indefinite.

III. NuVasive Does Not Infringe the '933 Patent as a Matter of Law.

A. Vitiation Bars Warsaw's Infringement Theory.

A claim is infringed only if each claim limitation is present in the accused device or method literally or under the doctrine of equivalents. *Seachange Int'l, Inc. v. C-Cor, Inc.*, 413 F.3d 1361, 1377 (Fed. Cir. 2005). NuVasive does not infringe the '933 patent because the accused retractors do not have a "working channel being enclosed by said first portion and said second portion between said distal and proximal ends."

(A275-78, A17-18.) Warsaw admitted this element is not literally present, (A10728-29), and vitiation bars use of the doctrine of equivalents.

"Under the 'all-elements rule,' a patentee may not assert 'a theory of equivalen[ce] [that] would entirely vitiate a particular claim element.'" *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1355 (Fed. Cir. 2010). The all-elements rule "empowers a court to perform again the standard insubstantial variation test for equivalency, but this time as a question of law." *Id.*

Warsaw's equivalence theory vitiates any limitation on the structure of the enclosed working channel. The claims as construed require the channel be enclosed by two blades with no gaps between them. (A17-18.) Warsaw's expert testified that the enclosed working channel formed by the three-blade NuVasive retractors is equivalent to the claimed two-blade channel because, either way, there is a closed corridor for the surgeon to access the disc space. (A10731-33, A10772.) But he also admitted that, under his theory of equivalence, a working channel with ***any*** number of blades would be equivalent to what is claimed. (A10772.) In other words, in Warsaw's view, a retractor with a working channel formed by three, four, six, or ten blades would be equivalent, so long as the blades formed a closed corridor. (*Id.*)

This cannot be right. The claim already requires that the working channel be "enclosed"—it then proceeds to specify a specific structure (two blades) that must form the enclosure. If *any* enclosed structure would be an equivalent—and that's what Warsaw proposed—then the result is to vitiate that limitation. The three-blade

structure of NuVasive's retractors thus cannot be equivalent to the claimed two-blade structure. *See, e.g., Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 651 F.3d 1318 (Fed. Cir. 2011) ("[W]e agree with Honda that finding a signal from one source to be equivalent to 'signals from a plurality of sources' would vitiate that claim limitation by rendering it meaningless."); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed. Cir. 1998) ("According to the expert testimony, *any* shape would be equivalent to the conical limitation of claims 2 and 10. Such a result is impermissible under the all-elements rule of *Warner-Jenkinson* because it would write the 'generally conical outer surface' limitation out of the claims.").

B. Warsaw Cannot Show the Working Channel is Enlargeable by Laterally Moving and Pivoting "Each" Blade.

Warsaw's infringement theory has another, independent legal problem. Warsaw attempted to prove infringement by taking a different position on what part of NuVasive's retractors constituted the claimed "first and second portions" when addressing different claim limitations involving those structures. (A10728-43, A10807-08.) But the claim language requires the "first and second portions" be the same structure throughout the claim. *See, e.g.*, *Intamin Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1333 (Fed. Cir. 2007) ("The use of the word 'said' in a claim refers to an earlier use of the term in the claim."). So if Warsaw is permitted to say that three blades are the equivalent of two to satisfy the initial part of the claim, it is also required to show that all three blades meet the second part of the claim—that "*each*"

blade laterally move and pivot. Warsaw cannot show that "each" of the three blades of NuVasive's retractors meets this requirement, (A10773-74; A11756-57), nor did it try to. There can thus be no infringement as a matter of law.

Warsaw never tried to prove that the structures it identified as the "working channel" and "first and second portions" in the accused products meet all the limitations the claim imposes on those structures. Its reason for doing this was simple: no structure meets all the requirements because no two blades enclose the working channel, (A10770-72), while not all three blades of NuVasive's retractors laterally move and pivot. (A10773-74; A11756-57.) So if Warsaw picked two blades of NuVasive's retractors as the "first and second" portions throughout the claim, then they would not meet the requirement that they "enclose" the working channel. And if Warsaw picked all three blades as the 'first and second portions" throughout the claim, then they wouldn't meet the requirement that "each" blade laterally move or pivot. Warsaw's attempted use of equivalents to cover a retractor that does not have this same relationship between the blades—namely, is not a retractor in which all the blades that enclose the working channel also laterally move and pivot—is impermissible as a matter of law. *See, e.g., Dolly, Inc. v. Spalding & Evenflo Cos., Inc.*, 16 F.3d 394, 399 (Fed. Cir. 1994) (finding no equivalents as a matter of law where the claim required a child's chair with a "stable frame" composed of something other than the seat and back panels and the patentee's theory of equivalence would eliminate this specific relationship of the various parts of the chair required by the claim).

IV. Warsaw's Lost Profits Theory Was Legally Impermissible.

If the Court lets any part of the liability judgment on the '973 or '933 stand, it should nevertheless reject Warsaw's legally erroneous "lost profits" theories and remand for a recalculation of the damages award.

A. Warsaw Was Not Entitled to Recover Money Transferred to It by Other Medtronic Entities as "Lost Profits" Damages.

"Whether lost profits are legally compensable in a particular situation is a question of law that we review *de novo*." *Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004). The general rule is that "if the patentee is not selling a product, by definition there can be no lost profits." *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1548 (Fed. Cir. 1995) (*en banc*). Moreover, the availability of lost profits does not turn "solely" on "a 'but for' test in the sense that an infringer must compensate a patentee for any and all damages that proceed from the act of patent infringement." *Id.* at 1546. Rather, the asserted harm must be "of the *type* for which the patentee may be compensated" because "judicial relief cannot redress every conceivable harm that can be traced to an alleged wrongdoing." *Id.*

Warsaw did not sell to outside customers any of the products for which it sought "lost profits." Instead, Warsaw sought to recover revenue that would have supposedly been realized by separate Medtronic entities that are not plaintiffs, and then transferred to Warsaw through: (1) a "true up" payment from MSD in which it gives everything over 5% of its profits to Warsaw; (2) transfer payments from MSD to

Warsaw for unpatented products that Warsaw sends to MSD; and (3) "royalties" paid to Warsaw from Medtronic manufacturing entities. (A11010-11.) None of these transfers, which are solely for tax purposes, creates a lost profits claim for Warsaw—these are not the "type" of damages that are appropriate, and Medtronic's internal contracting is an intervening event that cuts off any chain of causation from NuVasive's accused infringement. The Court should thus vacate and remand with instructions to limit damages to a royalty at the jury's rates.

This Court's decision in *Poly-America* demonstrates that Warsaw cannot recover money transferred to it by separate corporations. There, this Court prohibited a patentee (Poly-America) that was not selling products to outside customers—and, in fact, not selling anything at all—from collecting the "lost profits" of its sister company (Poly-Flex). *Poly-America*, 383 F.3d at 1310-12. The court explained that "the patentee needs to have been selling some item, the profits of which have been lost due to infringing sales, in order to claim damages consisting of lost profits." *Id.* at 1311. The reason is simple: companies who create complex corporate structures "must take the benefits with the burdens" and "may not enjoy the advantages of their separate corporate structure and, at the same time, avoid the consequential limitations of that structure." *Id.* The Court further found that a license between the companies stating that Poly-America "desires to have the contractual right to collect all damages accruing to Poly-Flex" still didn't entitle Poly-America to "lost profits" damages. *Id.* Parties "cannot create lost profits for a patentee if there are none. Awarding lost

profits to Poly-America on the basis of its private arrangement with Poly-Flex would synthetically create lost profits for Poly-America, when it may not have suffered any, to the detriment of [defendant]." *Id.* at 1311-12.

The situation here is materially identical. Warsaw (the patent holder) does not sell anything to outside customers (surgeons and hospitals) and thus does not compete with NuVasive. (A10907-09; A11096-97; A10889-90.) In particular, Warsaw does not make or sell implants or retractors (the products covered by the '973 and '933 patents), nor does it make or sell any of the items included in the "true up payment" or "lost royalties" categories of its claim—these products are made by Medtronic Deggendorf or third-parties, and all are sold by MSD. (*Id.*) The few unpatented items that Warsaw does make itself—rods and screws for fixation—are only "sold" to MSD, not any end customers. (*Id.*) Because Warsaw is not actually selling any items to end-customers in competition with NuVasive, it should be barred from recovering any of these intra-company transfers as "lost profits." *Poly-America*, 383 F.3d at 1310-12. Indeed, at least one district court has prohibited a patentee from recovering these types of tax-related intra-company transfers. *See, e.g., Fujitsu Ltd. v. Tellabs, Inc.*, 2013 WL 2285794 (N.D. Ill. May 23, 2013), *permission to appeal denied by* 2013 WL 5098993 (Fed. Cir. Sept. 11, 2013).

It should not matter that Warsaw supposedly receives this money itself under agreements with separate Medtronic entities. *Poly-America* holds that companies can't create lost profits by contract. *Id.* at 1311-12. That Warsaw's contracts are written in

terms of actual numbers (*e.g.*, Warsaw receives a 31% royalty from Deggendorf (A10890-92), and Warsaw receives everything over ~5% profit from MSD (A10935-36)), rather than a blanket conveyance of all damages, as in *Poly-America*, should not change the analysis. Warsaw is, in substance, trying the same thing prohibited by *Poly-America*: "synthetically" creating lost profits based on sales made by other Medtronic corporations. *Id.* The Court should not allow it.

B. There Should Be No Lost Profits on Unpatented Components.

Even if the Court determines Warsaw can collect intra-company payments as "lost profits," the damages award must still be vacated because it was based on the improper inclusion of unpatented items. A patentee may not recover damages on unpatented items "that have essentially no functional relationship to the patented invention and that may have been sold with an infringing device only as a matter of convenience or business advantage." *Am. Seating Co. v. USSC Group, Inc.*, 514 F.3d 1262, 1268 (Fed. Cir. 2008) (quoting *Rite-Hite*, 56 F.3d at 1550). "A functional relationship does not exist when independently operating patented and unpatented products are purchased as a package solely because of customer demand." *Id.* Warsaw failed to establish the requisite functional relationship and thus cannot recover damages for convoyed sales of these unpatented items.

The two major categories of unpatented components—fixation and biologics—can be and are frequently used independently of the patented implants and retractors. Warsaw's expert admitted a surgeon can use one company's

implant/retractors, while using another's fixation equipment and biologics. (A11119-22.) Surgeons performing NuVasive's XLIF procedure had frequently used Medtronic's fixation and biologics. (A11186-87; A11991-92, A12020-21. A12058-59.) Indeed, a majority of XLIFs were followed by the use of fixation equipment from a supplier other than NuVasive. (A12020-21.) Sometimes fixation is not used at all—the surgeon determines where it is necessary on a case-by-case basis, (A11186-87; A10617.) And when the surgeon does use fixation, it often involves an additional procedure where the surgeon flips the patient and makes a new incision. (A11119-20.) No asserted claim refers to fixation. All but one are silent on biologics. And the single claim that does reference biologics (claim 61 of the '973), just says the implant has to be capable of retaining them—a prior art feature.

There is even less evidence on the other unpatented components included in Warsaw's calculations, such as hooks, disposables, and other instruments. Warsaw's basis for including them was that each item was included together on the same invoice with a patented product. (A11002-04.) But most of the unpatented products are rarely used with the patented ones: ~90% of the unpatented products were used less than half the time, and ~80% were used less than 10% of the time. (A24925-26; A11111-15.) Several of these unpatented products can be and are in fact marketed and used in other, non-infringing procedures. (A11116-22.)

Given these undisputed facts, none of these unpatented items belonged in the damages calculations under this Court's precedent. *See, e.g.*, *American Seating*, 514 F.3d

at 1268-69 (setting aside a convoyed sales award where one company's patented wheelchair restraints could be used with another company's unpatented bus seats and "package sales were for reasons of convenience and 'one-stop shopping,' not because of an absolute requirement that the two items function together"); *Rite-Hite*, 56 F.3d at 1549-51 (prohibiting recovery for unpatented dock levers, even though "customers frequently solicited package bids for the simultaneous installation" of them with patented vehicle restraints because "each could effectively have been used independently of each other" and the package sales simply "facilitated contracting and construction scheduling"); *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009) (prohibiting recovery for unpatented braces and vests where they "can be used independently" and were "related only by virtue of the business relationship" formed with the surgeon from selling the patented screws).

Warsaw's inclusion of unpatented items was all the worse because neither the '973 nor '933 patents drove demand for the XLIF procedure, (A11033-34), a common requirement for the expansion of damages to unpatented components. *Rite-Hite*, 56 F.3d at 1549. Warsaw's expert admitted that NuVasive's patented nerve-monitoring technology was necessary for XLIF—so the '973 and '933 patents cannot have driven demand for the unpatented items in the XLIF surgical kits. (*Id.*) Moreover, Warsaw's expert admitted that the disparate market share between NuVasive's XLIF and Medtronic's DLIF, both of which involve implants which practice the '973, shows the '973 patent doesn't drive demand. (A11089-90.) Medtronic did not even practice the

'933 patent, and only some of NuVasive's retractor models for XLIF were accused as infringing, so the '933 patent cannot have driven demand either. (A11088.) The Court should thus vacate the damages award and remand for recalculation with all unpatented items excluded.

C. The Damages Award Must Be Vacated if the Judgment on the '973 or '933 Patent is Set Aside.

The damages award should also be vacated if the Court reverses or vacates the liability judgment on one but not both of Warsaw's remaining patents. The award covered all three Warsaw patents—the '973, '933, and the now-dismissed '586—and the jury was not asked to specify damages by patent. (A241-42.) There is no way to know what total damages were associated with each patent, which warrants a new trial on damages if some but not all of the liability findings are upheld. *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1309-10 (Fed. Cir. 2007).

D. The Ongoing Royalty Should Be Vacated If this Court Changes the Lost Profits Award.

Finally, if this Court affirms on liability in full or in part and vacates the damages judgment, it should also vacate the district court's ongoing royalty rates on Warsaw's patents. The court calculated its ongoing royalty in part by referring to the lost profits component of the jury's award. (A73-74.) Therefore, if the jury's award was excessive, the ongoing royalty should also be vacated so the district court can determine whether the reduction in past damages warrants a lower ongoing royalty.

V. If the Court Reaches Warsaw's Damages Appeal, It Should Affirm.

A. The District Court Correctly Denied Supplemental Damages.

The district court correctly denied Warsaw supplemental damages because it would have invaded the jury's province to assume they ignored part of the damages period where the instructions left them free to award damages through trial. (A30258-59.) This rationale is consistent with several other courts, which have denied supplemental damages for alleged pre-verdict infringement where, as here, (1) the jury instructions did not limit the damages period the jury could consider, and (2) the plaintiff could have presented evidence to the jury regarding how to estimate damages for infringement after the defendant's sales data ended but did not. *See, e.g., Apple, Inc. v. Samsung Elecs. Co., Ltd.*, 926 F. Supp. 1100, 1104-05 (N.D. Cal. 2013); *Presidio Components Inc. v. Am. Tech. Ceramics Corp.*, 2010 WL 3070370, at *2 n.1 (S.D.Cal. Aug. 5, 2010); *Oscar Mayer Foods Corp. v. Conagra, Inc.*, 869 F. Supp. 656, 668 (W.D. Wis. 1994). Although other district courts have reached a contrary conclusion, that only underscores that this is a matter to be entrusted to the trial judge to decide on the particular facts of the case. The district court did not abuse its discretion in denying supplemental damages here.

There is no reason to think the jury's award does not already include damages through trial. The jury was instructed to award damages to compensate for infringement and was given no cut-off date for when they should end their damages calculations. (A221, A223, A228.) The jury's natural assumption would be that they

should award damages through the trial date. Indeed, Warsaw's damages expert encouraged the jury to consider damages all the way through trial:

> Q. Finally, what's the time frame for assessing the but for world with infringement and without infringement?
>
> A. ***The time period starts from the beginning of the infringing sales and continues through the presence [sic: present]***….
>
> Q. Did you specifically quantify the damages that you believe Warsaw ***has suffered*** as a result of the infringement by NuVasive?
>
> A. I have.

(A10975.) And, although Warsaw's expert agreed that the "damage period for data [that] was actually available" ended in July 2010, (A11026), he encouraged the jury to award more to account for that:

> Q. Dr. Neels, the various sales data you were using for your calculating lost profits, do they go all the way through the present?
>
> A. They don't go quite all the way through the present. They go partway through Fiscal Year, 2011.
>
> ***
>
> ***Q. If you went through the present, there would be additional numbers?***
>
> ***A. There would be, yes.***

(A11012-13.) There was no reason for Warsaw to ask these questions if it were not encouraging the jury to award damages for the period after the sales data stopped. Indeed, Warsaw presented a range of calculations to the jury, ranging from $206-375 million (A11062-63)—testimony that invited the jury to pick a higher number within that range to ensure Warsaw was compensated for infringement through trial.

Moreover, if there is uncertainty about what period the jury's award covers, the district court did not abuse its discretion in resolving it against Warsaw. "The burden of proving damages falls on the patentee." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009). If Warsaw wanted to limit the jury's consideration of damages to infringement before July 2010, it should have asked for an instruction to that effect, or incorporated that into the verdict form. That would have been easy to do—the jury already received specific instructions on when to start the damages period. (A221, A223, A228.) Instead, Warsaw left the instructions silent on the end of the damages period, making it impossible to award supplemental damages while being sure that they do not amount to double-dipping. *Cf. Genlyte Thomas Group LLC v. Arch Lighting Group, Inc.*, 278 Fed. App'x 1004, 1008-09 (Fed. Cir. 2008) (non-precedential).

None of Warsaw's arguments requires a different result. Most are complaints about discovery and case management issues that do not demonstrate an abuse of discretion. Warsaw could have asked for supplemental sales data shortly before trial if it felt that was necessary to present its damages case through the verdict. It never did. Warsaw could have asked its expert to present further projections of damages through trial using testimony that there were about 1,500-2,000 XLIF procedures per month. (A11178.) It chose not to. Indeed, Warsaw failed to take these steps even though it amended another part of its damages calculations only days before trial began. (A3575-76.) The district judge, who was familiar with the discovery history and case

schedule, correctly determined this was a case like *Oscar Mayer*, (A30259), implying that Warsaw could have taken steps to present additional calculations but did not.

Warsaw's reliance on precedent addressing accountings for post-verdict damages—*e.g.*., *Ecolab, Inc. v. FMC Corp.*, 569 F.3d1335, 1353 n.5 (Fed. Cir. 2009)—is misplaced. The pre-verdict situation is different because Warsaw could have asked the jury to award damages through the date of the verdict. By contrast, it is impossible for a patentee to ask the jury to award post-verdict lost profits and running royalties for infringement that has not yet occurred.

Finally, Warsaw's complaints about being denied full compensation are misplaced. The jury may well have awarded Warsaw damages through the trial date, as Warsaw's expert twice encouraged it to do. The jury could have done so without violating the instruction against "speculation"—it had Warsaw's (flawed) model regarding the damages attributable to each XLIF, (*e.g.*, A11006), and an estimate of monthly XLIF procedures. (A11178.) To the extent the jury didn't award damages for the entire period, that simply reflects Warsaw's failure to meet its burden of proof by taking steps to collect and present damages evidence addressing the period through trial. So, if the Court reaches this issue, it should affirm the district court.

B. If the Court Affirms on Liability and Damages, the Ongoing Royalty Was Not an Abuse of Discretion.

This Court reviews the district court's ongoing royalty rate for abuse of discretion. *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1315 (Fed. Cir. 2009). The

district court carefully considered all the relevant evidence and, based on the "particular circumstances" here, selected rates between the parties' proposals and higher than the jury's rates. The court properly found that this would adequately compensate Warsaw for the potential lost sales of its corporate affiliates, while correctly choosing a rate consistent with the public interest in continued availability of NuVasive's accused products. Therefore, if this Court leaves the jury's full damages award intact, it should affirm the ongoing royalty rates.

The court acted within its discretion when setting the royalty. The court began with the rates that Warsaw had presented at trial—25% for the '973 and 15% for the '933—which Warsaw told the jury were "the amount Warsaw would be willing to accept for forego its own sales, *i.e.*, the value it would require to permit NuVasive to compete in the marketplace." (A72.) Using the '973 patent as an example, the court correctly found "nothing in the parties' post-negotiation relationship that was not already accounted for in Warsaw's pre-verdict negotiation analysis" to support Warsaw's contention that a 36% royalty was appropriate. (*Id.*) In particular, the court found that, "in this case," no post-verdict enhancement for willfulness was appropriate because NuVasive's accused products "provide needed medical relief to patients" and "doctors who favor defendant's medical procedures cannot readily change to other methods of devices." (*Id.*) So the court used Warsaw's rates from trial as the starting point, and then, correctly noting that "the jury found that the profits Warsaw forfeits are substantially less than the amounts Warsaw proposed at

trial," (A73), adjusted those rates accordingly. Observing that the jury awarded only 55% of one of Warsaw's alternative lost profits demands ($75.2 million of $137 million), the court set the ongoing royalties at 55% of Warsaw's pre-verdict demand—*i.e.*, 25% x 55% = 13.75% for the '973, and 15% x 55% = 8.25% for the '933 patent. (A73-74.) The Court's analysis here was conservative because another of Warsaw's alternate lost profits calculations demanded as much as $321.4 million. (A11053-54; A68-69 n.3.) If the court has used this number, the downward adjustment would have been much more. The court further supported its analysis because Warsaw no longer had "the threat of a permanent injunction" in its "post-judgment arsenal," unlike in the pre-verdict hypothetical negotiation. (A73.) Despite these adjustments, the ongoing rates were still higher than the jury's rates for pre-verdict infringement, and in the case of the '933 patent, nearly triple the jury's rate. So the court did not abuse its discretion by concluding that these rates "will reasonably compensate Warsaw for the ongoing use of its patents and sufficiently incorporate compensation for NuVasive's competitive sales." (A73.)

Warsaw's complaints at p. 37-49 that the ongoing royalty does not provide "adequate compensation" are unfounded. For one thing, Warsaw wrongly generalizes when arguing that the post-verdict royalty should always be much higher than the pre-verdict royalty. Each case is different. Here, the district court increased the ongoing royalty rate when compared to the jury's pre-verdict rate—just not as much as Warsaw wanted. The court did not abuse its discretion when finding that the strong

public interest in XLIF's continued availability weighed against an even larger increase. This Court's decision in *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 670 F.3d 1171, *as modified on rehearing*, 682 F.3d 1003 (Fed. Cir. 2012), does not require a different result. *Bard* found no abuse of discretion in increasing a royalty rate from the 10% rate found by the jury to 12.5%-20%, depending on the product. This does not imply that a lesser increase would have been an abuse of discretion, there or here. The concept of discretion necessarily entails giving district courts leeway to craft a remedy appropriate to the facts before them. Moreover, the district court increased the rate on the '973 patent in a similar manner as *Bard*, and it increased the rate on the '933 patent by a greater factor than *Bard*.

For another thing, Warsaw is incorrect to argue that the district court's ongoing royalty did not account for competition and lost profits. The court explicitly said that it was taking this into account, (A70), and it did so by starting from rates that Warsaw had told the jury included a component for lost sales. (A70, A72-74.) The court did not abuse its discretion by using its own methodology to determine appropriate compensation for this harm. Indeed, Warsaw's methodology assumed (without evidence) that it will continue to lose profits at the same rate in the future as it supposedly did in the past, even though the market conditions could change. Moreover, Warsaw erroneously included the jury's award for all three patents (including the now-dismissed '586 patent) in its calculation, even though there is no way to know how much of the lost profits related to the remaining '973 and '933

patents instead of the dismissed '586. The district court was not required to accept this speculative approach.

Warsaw also errs at p. 47-49 when asking the Court to expand the royalty base on the '933 patent to include unpatented fixation (*e.g.*, rods and screws). As an initial matter, Warsaw did not properly preserve the argument because, as the district court found, the argument was not developed in the ongoing royalty briefing and was first made in a motion to reconsider. (A76.) That said, it would be inappropriate to include these unpatented items in the royalty base because Warsaw has not established the legal prerequisites for doing so. It never tries to show the '933 patent is the basis of customer demand for the unpatented rods and screws, and its expert conceded that it is not. (A11033-34, A11088.) The issue is not, as Warsaw suggests, a failure to compensate for all infringing acts of use, but rather the district court's correct decision not to permit Warsaw to sweep unpatented items into the royalty base.

Therefore, if the Court upholds the full jury verdict for past infringement, it should find no abuse of discretion in the ongoing royalty. That said, the most Warsaw could obtain is a remand for the district court to reconsider the royalty and exercise its discretion in the first instance—it would be premature for this Court to set a royalty without first giving the district court an opportunity to reconsider matters in light of this Court's opinion. *Paice*, 504 F.3d at 1315.

VI. The Court Should Affirm on the '236 Patent.

A. The District Court Correctly Construed the "Stopping" Step.

The district court correctly construed the term "stopping the emission of said stimulus signal immediately after said predetermined neuro-muscular response is detected." (A22.) The dispute is whether the "stopping" step requires permanently stopping the signal (as Medtronic believes) or is instead satisfied once the signal stops, even if a new signal later starts (as the district court determined). The district court's construction, which is consistent with the surrounding claim language, the specification, and the file history, should be affirmed.

The claims demonstrate that the "stopping" step does not require permanently stopping the stimulus signal. Claim 1 is a comprising claim, and the words "permanently" or "without restarting" do not appear in the stopping step. The claim thus leaves open the possibility of additional steps, including the emission of a new stimulus signal. Dependent claims 5 and 9 confirm that the stopping step does not require permanent cessation of the signal. Both claims require repeating the method of claim 1, either automatically or with varying signal intensity. (A300 at 18:15-20, 18:25-28.) It would be impossible to satisfy these claims if claim 1 required permanently stopping the signal because claims 5 and 9 require restarting it.

The specification likewise demonstrates that "stopping" does not require permanently stopping the signal. It identifies rapidly repeating the method as the preferred embodiment: "[p]referably, the sensing of whether a nerve is positioned

adjacent to a surgical tool/probe is continuously repeated in very short intervals of time, such that the operator can be warned in real time as the surgical tool/probe is advanced toward the nerve." (A299 at 16:15-19.) Medtronic's proposed construction, which precludes a repeating signal, would thus exclude the preferred embodiment from all the asserted claims, a result that is "rarely, if ever, correct," and is wrong here. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

The prosecution history also supports the district court's construction. The '236 patent differed from the prior art primarily because it applied nerve-monitoring to lateral spinal surgery. The PTO acknowledged "that none of the cited references teach a lateral approach to the spine," (A22171), and, after NuVasive amended what became claim 1 to clarify that it involved detecting nerves extending laterally from the spine, (A22167), the PTO allowed it. (A22183.) Medtronic's reliance on another part of that amendment, in which NuVasive added the "stopping" step and discussed the Raymond '153 patent, is misplaced. NuVasive added the stopping step to emphasize the invention avoids "the unnecessary stimulation" found in prior methods, but it never said the claims require *permanently* stopping the signal:

> Claim 15 [which became issued claim 1] has also been amended to reflect that the emission of the stimulus signal is immediately stopped after the predetermined neuro-muscular response is detected. This is a safety mechanism designed to remove the stimulation of the spinal nerve during the processing time required to communicate the intensity level to a user (e.g. surgeon or other operating room personnel) and during the time required for the user to make a determination of the proximity of the spinal nerve to the probe or surgical tool based on the communicated intensity level (e.g. not close-free to continue towards lateral aspect; relatively close-use caution when

> proceeding towards lateral aspect; too close - do not proceed towards lateral aspect)
>
> This avoids the unnecessary stimulation found, for example, in the Raymond '153 reference. More specifically, as evident in Col 3, lines 28-32, Raymond '153 teaches that "The amount of current generated by the electrical source is automatically controlled so as to maintain the signal generated as a function of the response of the nerve to the stimuli."

(A22173.) Instead, NuVasive was distinguishing between immediately stopping the stimulus signal (as the '236 patent requires) and decreasing the signal but still maintaining it at a level sufficient to constantly evoke a neuromuscular response (as Raymond '153 did)—not between permanently stopping the signal and temporarily stopping it. Dr. Raymond himself explained that he read the file history and did not understand it to make the disclaimer that Medtronic says it does. (A11315-16.) Medtronic cannot meet the "clear and unmistakable" standard for disclaimer where even the person whose work was distinguished thinks there is no disclaimer.

NuVasive is not, contrary to Medtronic's argument at p. 55-56, contesting that it is bound by its statements to the PTO. The problem for Medtronic is that those statements don't actually disclaim what Medtronic says they do. None of the intrinsic evidence supports limiting the stopping step to permanent cessation of the stimulus signal. The district court's construction should thus be affirmed.

B. The District Court Correctly Construed "Stimulus Signal."

The district court correctly construed "stimulus signal" to mean "an electrical signal for eliciting a neuromuscular response." (A21-22.) There were only two

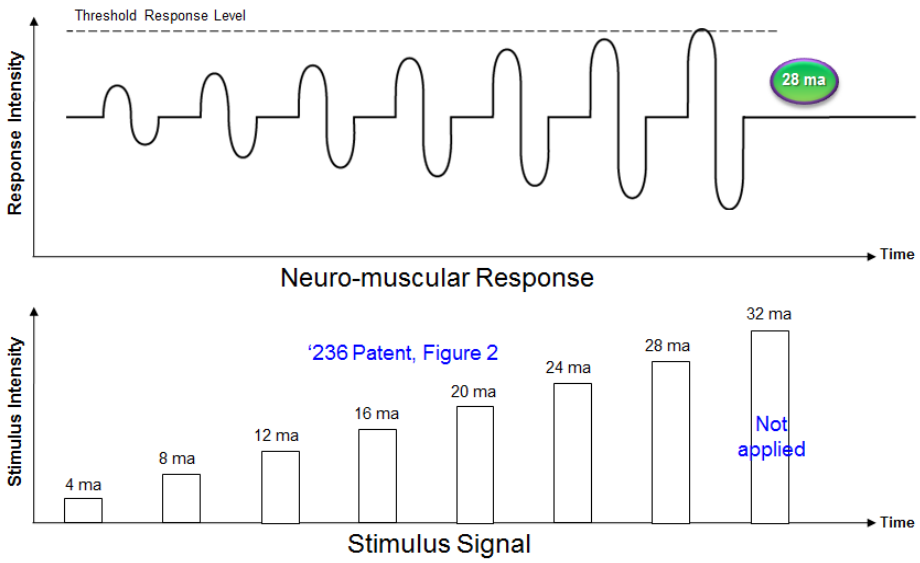
differences between the parties' constructions—(1) whether the signal must be "electrical" and (2) whether the signal is for eliciting a neuromuscular response. The claim language and specification show that the stimulus signal is electrical. (A292-96 at 2:19-23, 5:31-37, 9:13-21.) Moreover, the claim language links the stimulus signal to eliciting a pre-determined neuromuscular response at least five times. (A300 at 17:54-18:5.) It is not surprising, then, that Medtronic conceded in the district court that the stimulus signal was both electrical and exists for the purpose of eliciting a neuro-muscular response. (A1871.) That should be the end of the issue.

Instead, Medtronic asserts at p. 57 that the district court's construction includes "redundant" language that is elsewhere in the claim. But, if anything, this reinforces the correctness of the construction—consistency with the surrounding claim language is a good thing. Moreover, as discussed below, Medtronic is wrong to say that NuVasive misused the construction at trial. The bottom line is that Medtronic fails to demonstrate why its broader construction—which could sweep in all sorts of signals never contemplated by the patent (like radio and magnetic waves)—is correct.

C. Substantial Evidence Supported the Jury's Conclusion that Use of NIM-Eclipse Meets the "Stopping" Limitation.

Substantial evidence supports the jury's finding that use of NIM-Eclipse's "Nerve Proximity Mode" in DLIF procedures directly infringes the '236 patent. Dr. Raymond explained the operation of Nerve Proximity Mode—based both on his review of Medtronic's documents describing its functionality and his personal testing

of the product—and explained how it meets each claim limitation. (A11280-312, A11369-76.) The NIM-Eclipse emits a stimulus signal and increases the signal's intensity level until the signal elicits a predetermined neuromusculuar response, similar to what is illustrated below. (A11285-93, A11298-304, A11308-11, A18876-77; A11278-95; A16348-50; A17922-23; A17903; A16261; A17956-65.)



Once it detects that response, NIM-Eclipse stops that stimulus signal and communicates the intensity level needed to elicit the response to the person operating the device (28 mA in the example above). (*Id.*) At this point, the cycle repeats: the NIM-Eclipse begins emitting a new stimulus signal, starting back at a lower intensity, and then increases the intensity of that signal until a pre-determined response is detected; it stops the signal and communicates the response. (*Id.*) And so on. (*Id.*) Each iteration of these four steps is a performance of the method of claim 1, (A11309-12, A11333-35, A11373-75), and NIM-Eclipse likewise infringes claims 5

and 9 because it automatically repeats the steps and varies the signal's intensity level as it does. (A11302-03.)

Medtronic wrongly asserts at p. 58 that Dr. Raymond "admitted" that "neither NIM-Eclipse nor the Raymond '153 patent stop the stimulus signal." In fact, he said the opposite:

> Q. It's true, isn't it, that because the stimulus pulses of your '153 patent continue to be emitted at a regular frequency, that the stimulus signal does not stop.
>
> A. ***No***.

(A11352; *see also* A11363-64 (same for the NIM-Eclipse).) What Dr. Raymond did acknowledge is that the NIM-Eclipse continues to emit *pulses*, even after it detects a neuro-muscular response. (A11352.) But that is irrelevant to infringement because, as Dr. Raymond explained, one stimulus *signal* stops once the response is detected and a new signal begins with the next pulse. (A11370-75.) Medtronic may have had a different interpretation of which pulses belong to which signal. But it called no expert of its own on this issue, and the jury was entitled to credit Dr. Raymond's testimony over Medtronic's attorney argument. Medtronic's "surrender" argument at p. 59 fails for the same reasons as its disclaimer argument—the claims do not require permanent stopping.

Medtronic's non-infringement arguments on "stimulus signal" at p. 59-61 are similarly incorrect. The jury was entitled to credit Dr. Raymond's interpretation of the "stimulus signal" over Warsaw's attorney argument. No more need be said to

demonstrate that substantial evidence supports the jury's finding that use of NIM-Eclipse in Nerve Proximity Mode in a DLIF constitutes infringement.

D. Substantial Evidence Showed the Other Elements of Indirect Infringement.

Having found that doctors who use the accused functionality directly infringe the '236 patent, the jury also properly found that Medtronic induced and contributed to infringement by these doctors.

1. The Jury Properly Inferred Medtronic Knew or Was Willfully Blind to Inducing Infringement.

Medtronic's intent is a question of fact, and the jury reasonably found that Medtronic intended to induce infringement. *See, e.g., Broadcom Corp. v. Qualcomm Inc.,* 543 F.3d 683, 700-01 (Fed. Cir. 2008). NuVasive notified Medtronic of its likely infringement in a June 2009 letter, and then counterclaimed for infringement in August 2009. (A3244-45; A30492-94.) Despite these warnings, Medtronic continued to instruct surgeons to use the "Nerve Proximity Mode" of NIM-Eclipse in an infringing manner. (A11278-95; A16348-50; A17922-23; A17903; A16261; A17956-65.) The jury was correctly instructed on the law and therefore understood that Medtronic could be liable for inducement only if Medtronic knew that it was both inducing these acts and inducing infringement (or was willfully blind). (A213.) Substantial evidence supports the jury's inference that Medtronic had the requisite knowledge and intent based on these facts. *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S.Ct. 2060, 2071-72 (2011). Neither of Medtronic's cases holds otherwise—

Global-Tech found the defendant *did* have the requisite knowledge, while *Commil* simply reinforces that the defendant's intent is a matter entrusted to a properly instructed fact-finder, like the jury here.

2. There Were No Substantial Non-Infringing Uses of the "Nerve Proximity Mode" of NIM-Eclipse.

The jury also reasonably found contributory infringement because the "Nerve Proximity Mode" of NIM-Eclipse is especially made for use in an infringing manner (*i.e.*, with the DLIF procedure) and lacks "substantial" non-infringing uses. Medtronic's product manuals for DLIF lateral procedures describe using "Nerve Proximity Mode" to traverse the psoas, and Medtronic employees have watched hundreds of DLIFs that use it. (A11278-95; A17922-23; A17903; A16261.) Although the NIM-Eclipse Manual refers to other procedures, (A16289), Medtronic cited no evidence that these procedures would use "Nerve Proximity Mode," as opposed to some other mode of the NIM-Eclipse device, much less that such uses would be "substantial." The jury's finding was thus well-supported. *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1379-80 (Fed. Cir. 2001) (jury reasonably found a component had no substantial noninfringing uses where defendant's product manuals stated it was to be used for the claimed medical procedure and there was no evidence of "actual uses of the device" in other procedures); *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010) ("Despite Microsoft's contention to the contrary,

evidence that some users saved XML documents in these noninfringing formats does not render the jury's verdict unreasonable.").

CONCLUSION

For the reasons above, the Court should affirm the judgment on the '236 patent, and reverse and remand on the '973 and '933 patents.

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Respectfully submitted,

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CERTIFICATE OF SERVICE AND FILING

I certify that I electronically filed the foregoing document using the Court's CM/ECF filing system. Counsel was served via CM/ECF on February 3, 2014.

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CERTIFICATE OF COMPLIANCE

The undersigned attorney certifies that the opening brief for NuVasive, Inc. complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B). The relevant portions of the brief, including all footnotes, contain 16,382 words as determined by Microsoft Word.

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